UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VINCENT DANG, *et al.*, Plaintiffs, v. AMARIN CORPORATION PLC, *et al.*, Defendants.	Civil Action No. 21-19212 (RK) (TJB) **OPINION**

KIRSCH, District Judge

THIS MATTER comes before the Court on a Motion to Dismiss the Amended Class Action Complaint (the "Motion") filed by Defendants Amarin Corporation plc ("Amarin"), John F. Thero, Michael W. Kalb, and Joseph T. Kennedy (together, "Defendants"). (ECF No. 58.) The Court has carefully considered the parties' submissions and resolves the matter without oral argument pursuant to Federal Rule of Civil Procedure 78 and Local Civil Rule 78.1. For the reasons set forth below, Defendants' Motion to Dismiss is **GRANTED** and all three counts of the Amended Consolidated Class Action Complaint (the "Amended Complaint"), (Am. Compl., ECF No. 50), are **DISMISSED** without prejudice.

I. BACKGROUND

This is a putative securities fraud class action brought on behalf of purchasers of Amarin's American Depositary Shares ("ADSs") during a two-and-a-half year period from September 24, 2018 to April 12, 2021 (the "Class Period"). Plaintiffs are the 1199SEIU Health Care Employees Pension Fund and Warren Drabek ("Drabek"). The suit alleges that Defendants—Amarin and three of its officers—made material misstatements or omissions about Amarin's pharmaceutical product Vascepa, developments in Vascepa-related patent litigation, and Vascepa's financial prospects.

These assurances allegedly caused Amarin's share prices to remain artificially high, during which time the officers sold millions of dollars' worth of Amarin stock. When Amarin lost litigation over certain of its patents for Vascepa, the company's share price dropped and Plaintiffs suffered significant losses.

The facts below are taken from the Amended Complaint and assumed to be true solely for the purposes of deciding the pending Motion.

A. AMARIN AND VASCEPA

Amarin is a pharmaceutical company whose only product is Vascepa, a purified fish oil made up of 96% eicosapentaenoic acid ("EPA"), an omega-3 fatty acid extracted from fish. (Compl. ¶¶ 2, 28–29.) Pure EPA is known to "lower triglycerides and lipoproteins in the blood without increasing cholesterol." (*Id.* ¶ 2.) One type of lipoprotein, an apolipoprotein called "ApoB," moves cholesterol throughout the body, including "bad" cholesterol called high-density lipoprotein cholesterol ("LDL-C"). (*Id.* ¶ 33.) People with elevated levels of triglycerides, ApoB, and LDL-C are at a higher risk for heart attacks and strokes, and use of pure EPA is known to "decrease[] the risk of cardiovascular events, strokes, and other negative medical outcomes." (*Id.* ¶¶ 2, 33.)

In 1990, a Japanese company launched a purified EPA product called Epadel in Japan; studies in the early 2000s showed that Epadel had positive results in lowering triglycerides, lipoproteins, cholesterol, and cardiovascular risk. (*Id.* ¶¶ 3, 35.) Amarin has acknowledged that Epadel is pharmacologically equivalent to Vascepa. (*Id.* ¶ 35.) Several studies of Epadel, of which Amarin was aware, showed the positive effects of pure EPA on different patient populations. (*Id.* ¶¶ 3, 35–36.)

In 2013, Amarin launched Vascepa as the first purified EPA drug introduced to the U.S. market. (*Id.* ¶¶ 2–3.) The Amended Complaint alleges that since 2013, Vascepa has been Amarin's "only actual or prospective product" and that the company's profitability depended solely on Vascepa's success, resulting in the company's executives and investors focusing exclusively on issues surrounding Vascepa. (*Id.* ¶¶ 29–30; *see also id.* ¶¶ 156–69 (alleging Vascepa's importance to Amarin and its executives and quoting Defendants' statements about Vascepa).)

B. MARINE Trial and New Chemical Entity Application

In late 2009, Amarin launched a clinical trial entitled "Efficacy and Safety of AMR101 (Ethyl Icosapentate) in Patients With Fasting Triglyceride (Tg) Levels ≥ 500 and ≤ 2000 mg/dL" (the "MARINE Trial") to demonstrate that Vascepa meaningfully reduces triglyceride levels in patients with severely high triglyceride levels. (*Id.* ¶ 51.) While studies in Japan had already established that pure EPA would reduce triglyceride levels, the MARINE Trial was the first U.S. study to do so. (*Id.*) The MARINE Trial concluded in July 2011, after which Amarin submitted the trial data to the U.S. Food and Drug Administration ("FDA"). (*Id.* ¶¶ 51–52.) On July 26, 2012, the FDA approved Vascepa for treatment of patients with severely high triglyceride levels. (*Id.* ¶ 52.) Amarin was the first company to gain FDA approval for an EPA drug in the United States. (*Id.* ¶ 51.)

C. Patent Application before the USPTO and the Kurabayashi Study

Amarin applied for a U.S. patent for Vascepa in 2010. (*Id.* ¶ 53.) Receiving patent protection would grant Amarin intellectual property rights as the patent owner, along with a 20-year market exclusivity period for Vascepa. (*Id.* ¶¶ 5, 38, 45, 50.)

To qualify for patent protection, a drug invention must be useful, novel, and non-obvious. (*Id.* ¶ 45.) A drug invention is useful if it provides a tangible benefit. (*Id.* (citing 35 U.S.C. § 101).)

A drug invention is novel if it is not currently "in public use, on sale, or otherwise available to the public." (*Id.* (quoting 35 U.S.C. § 102).) Finally, a drug invention is non-obvious when it is "distinct enough from existing drug[inventions] that its invention would not be obvious to 'a person having ordinary skill in the art to which the claimed invention pertains.'" (*Id.* (quoting 35 U.S.C. § 103).) When assessing the obviousness prong, a patent examiner considers the "prior art," which comprises all "information known publicly before the effective filing date of a U.S. patent application," including information contained in foreign patents and patent applications, journal articles, and scientific papers. (*Id.* ¶ 46 (citation not provided).) Also relevant are whether there are "secondary considerations" of non-obviousness, including "unexpected results created by the claimed invention." (*Id.* ¶ 47.)[1]

An applicant seeking a patent must submit an application to the U.S. Patent and Trademark Office ("USPTO"), whose examiners assess whether the application merits patent protection. (*Id.* ¶ 45.) During the application process, an applicant must file a Form PTO-1449 ("Form 1449") disclosing prior art "known to the applicant to be material to the patentability of the claims in the application." (*Id.* ¶ 54.) Form 1449's requirement dovetails with the "duty of candor and good faith in dealing with the USPTO" laid out in 37 C.F.R. § 1.56 ("Rule 56"), which likewise requires disclosure of information material to patentability. (*Id.* ¶ 49.) The Amended Complaint alleges that an applicant would violate Rule 56 if they were to "engage in 'inequitable conduct,' or intentionally mislead the USPTO about material information." (*Id.*) Plaintiffs state that "[o]ne form

[1] *See also* 35 U.S.C. § 103 (A patent is invalid as obvious "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains."); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966) (whether a patent claim is obvious requires considering (1) "the scope and content of the prior art"; (2) "the level of ordinary skill in the pertinent art"; (3) the "differences between the prior art and the claims at issue"; and (4) "[s]uch secondary considerations as commercial success, long-felt but unsolved needs, [and the] failure of others").

of inequitable conduct is to 'bury' highly material prior art in a long list of references in an effort to conceal the piece of material prior art from the examiner." (*Id.*)

Amarin submitted its patent application related to Vascepa to the USPTO in February 2010. (*Id.* ¶ 53.) The application was titled "Methods of Treating Hypertriglyceridemia." (*Id.*) As Plaintiffs allege, the "crux" of the patent application was a method of treating patients with heightened triglyceride levels—between 500 and 1,500 mg/dL—with "4 grams of 96% purified EPA over a 12-week period." (*Id.*) From its initial application, Amarin claimed that the MARINE Trial resulted in "a reduction in triglycerides and ApoB without raising LDL-C levels." (*Id.*) The patent examiner rejected Amarin's application four times between June 20, 2011 and March 2, 2012. (*Id.* ¶¶ 56–70.) After each rejection, Amarin made new submissions responding to the bases on which the examiner rejected the application. (*Id.*) As the Amended Complaint describes, the examiner's first two rejections rested in part on the fact that based on the prior art, it was obvious that EPA administration would reduce triglycerides without increasing LDL-C levels. (*Id.* ¶¶ 56, 58.) Plaintiffs allege that in its responses to the first and second rejections, Amarin "focused almost exclusively" on how the reduction of triglycerides and decrease or non-increase in LDL-C from Vascepa was not "obvious in light of the prior art." (*Id.* ¶ 62; *see also id.* ¶¶ 57, 60.) After the third and fourth rejections, Amarin "dramatically changed its strategy" to argue in its third and fourth responses that the reduction in ApoB—rather than the non-increase in LDL-C—was unexpected and merited patent protection. (*Id.* ¶ 63; *see id.* ¶¶ 64–66, 68–70.)

After Amarin responded to the fourth rejection, the USPTO granted Vascepa's patents on July 26, 2012. (*Id.* ¶¶ 7, 68.) In the official Notice of Allowance published several months later, the examiner agreed with Amarin that a reduction in ApoB from treatment with purified EPA was an unexpected result. (*Id.* ¶ 71.) The examiner wrote that the "prior art is either silent or teaches

that there is no statistically significant change in Apo-B levels when patients with [triglyceride] levels less than 150 mg/dl or between 150-499 mg/dl are treated with [] 96% pure ethyl-EPA . . . ." (*Id.* ¶ 71 (emphasis omitted) (quoting the examiner's decision).) While the examiner found that "the claims in the patent were *prima facie* obvious based on the prior art," the unexpected result (a secondary consideration) of the reduction in ApoB helped overcome the *prima facie* finding of obviousness. (*Id.*)[2]

As part of its application, Amarin submitted its first Form 1449 to the USPTO on May 23, 2011 that included 29 previously published studies and 6 previously issued U.S. patents. (*Id.* ¶ 55.) Shortly afterwards, Amarin submitted a second Form 1449 on June 3, 2011—several weeks before the examiner rejected Amarin's application for the first time—that included over 300 references to prior art studies and papers and over 50 previously issued U.S. and foreign patents. (*Id.*) Among the references in its second Form 1449, Amarin included a paper published in 2000 about a Japanese study entitled "[EPA] Effect on Hyperlipidemia in Menopausal Japanese Women" (the "Kurabayashi Study"). (*Id.* ¶¶ 6, 35, 55.) The Amended Complaint alleges that the Kurabayashi Study "found that pure EPA lowers triglycerides without increasing LDL-C but also has a 'stimulatory effect on lipoprotein degradation' which resulted in significantly lower ApoB levels . . . ." (*Id.* ¶ 35 (citation not provided).) Amarin was aware of the Kurabayashi Study "well before" it applied for a patent, as it "cited to [the study] as evidence to investors that Vascepa could treat patients with elevated triglycerides." (*Id.* ¶ 6.)

Plaintiffs allege that Amarin violated its duty of candor to the USPTO by not specifically raising and discussing the Kurabayashi Study in its multiple responses to the patent examiner, in

[2] Amarin subsequently received additional patents related to Vascepa, which were continuations of this first patent. (Am. Compl. ¶ 72.) The District Court decision invalidating these patents, described below, describes the patents, which are each entitled "methods of treating hypertriglyceridemia." *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 449 F. Supp. 3d 967, 971–72 (D. Nev. 2020).

which Amarin discussed its argument that a reduction in ApoB was unexpected and not supported by the prior art. (*Id.* ¶¶ 64–70.) The Amended Complaint quotes Amarin's submissions to the USPTO, in which Amarin wrote that the "claimed reduction in [ApoB] is unexpected in view of the prior art of record" and discussed studies other than the Kurabayashi Study, (*id.* ¶ 64), and that "the successful reduction of apoB compared to a control group was entirely unexpected," (*id.* ¶ 66 (emphasis omitted)). Plaintiffs allege that Amarin "concealed" the Kurabayashi Study by "burying" it in the reference list of prior art included with its June 2011 Form 1449, (*id.* ¶ 7), even though the study "demonstrated the exact outcome that Amarin claimed was unexpected," (*id.* ¶ 65).

D. NEW CHEMICAL ENTITY STATUS AND THE NEVADA PATENT LITIGATION

While seeking patent protection for its treatment method using Vascepa, Amarin also applied to the FDA to designate Vascepa as a new chemical entity ("NCE"). (*Id.* ¶ 4.) This designation is available for a drug with an active ingredient the FDA has not previously approved. (*Id.* ¶ 42.) Classification as an NCE grants a drugmaker five years of regulatory exclusivity, during which time competitors cannot apply to the FDA to sell generic versions of the drug without conducting their own trials. (*Id.* ¶¶ 4, 42.) However, a competitor filing an Abbreviated New Drug Application ("ANDA") for a drug that is the bioequivalent of a patent-protected, designated NCE may certify that the patent for the NCE is invalid, unenforceable, or otherwise will not be infringed by the sale of the competitor's drug (a "Paragraph IV Certification"). (*Id.* ¶¶ 41–43.) In that case, the competitor may file their ANDA after only four years of NCE exclusivity, after which the patent holder may sue the ANDA-filer for patent infringement. (*Id.* ¶¶ 43–44.)

On July 26, 2016—four years after receiving patent-protection and the first day permitted under the regulatory exclusivity rules—three Amarin competitors filed ANDAs for generic

versions of Vascepa, accompanied by Paragraph IV Certifications. (*Id.* ¶ 73.) Shortly afterwards, Amarin sued all three companies for infringement in federal district court in Nevada (the "Nevada Litigation"). (*Id.* ¶ 74.) Amarin settled with one competitor but proceeded to litigate its patents' validity against the remaining two in a consolidated action. (*Id.*) Amarin's competitors argued that Amarin's method patent was an obvious innovation from a prior art and that the USPTO examiner had overlooked (and Amarin had not highlighted) the relevant prior art from Japan. (*Id.* ¶ 75.) The competitors specifically cited the Kurabayashi Study's finding that patients treated with purified EPA experienced statistically significant reduction in ApoB to argue that the examiner erred in finding that the MARINE Trial produced unexpected results that overcame the *prima facie* finding of obviousness. (*Id.*)

After a bench trial, the Honorable Miranda M. Du, U.S.D.C., invalidated the patents as obvious in a 70-page March 30, 2020 decision. (*Id.* ¶ 76); *see also Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 449 F. Supp. 3d 967, 971 (D. Nev.), *aff'd*, 819 F. App'x 932 (Fed. Cir. 2020). In her factual findings, Judge Du reviewed six studies the Court found were relevant prior art, including the Kurabayashi Study. *Id.* at 985–91. Regarding the Kurabayashi Study, Judge Du wrote that the study's administration of purified EPA with another drug (estriol, known to elevate triglyceride levels) for 48 weeks to the patient population of hyperlipidemic, menopausal women, would lead a person of ordinary skill in the art to attribute the reduction in ApoB found in the study to EPA. *Id.* at 989–90. Like the USPTO's examiner, Judge Du ruled that the prior art rendered the patents "*prima facie* obvious." *Id.* at 1007–09. Judge Du found that "the prior art showed that purified EPA produced each of the claimed effects in clinical studies," including that the "Kurabayashi [Study] disclosed that EPA reduced Apo B." *Id.* at 1007. Finally, as relevant here, Judge Du, unlike the patent examiner, found that the "positive lipid effects" Amarin relied on were

not "unexpected benefits" constituting a secondary consideration, because "Kurabayashi suggested that EPA reduced Apo B levels" and the examiner "did not consider Kurabayashi." *Id.* at 1013. The Court of Appeals for the Federal Circuit affirmed the decision on September 3, 2020, (Am. Compl. ¶ 14), and the Supreme Court denied *certiorari*, *see Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 141 S. Ct. 2794 (2021).

E. REDUCE-IT TRIAL

In November 2011, Amarin launched a clinical trial (the "REDUCE-IT Trial") to demonstrate that Vascepa reduced the likelihood of "cardiovascular events" in patients with elevated triglycerides who were already taking a statin medication to lower cholesterol. (*Id.* ¶ 77.) Years prior, a 2007 paper published in Japan (the "JELIS Study") had demonstrated that Epadel reduced cardiovascular risk in a statistically significant way. (*Id.* ¶ 79.) Amarin's executives were aware of the JELIS Study and expected the REDUCE-IT Trial to mirror its results. (*Id.*) Amarin publicly stated that if the REDUCE-IT Trial "succeeded in showing that Vascepa lowered cardiovascular risk, then the use and profitability of Vascepa would exponentially increase." (*Id.* ¶ 78.)[3]

On September 24, 2018, Amarin announced that the REDUCE-IT Study had "met its primary endpoint," demonstrating that "patients taking purified EPA were at substantially less risk for a cardiovascular event than patients taking a placebo." (*Id.* ¶ 80.)

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[3] Judge Du discussed the REDUCE-IT Trial in finding that the secondary considerations did not support finding Amarin's method patents non-obvious because there was no nexus between the REDUCE-IT Trial's results and the challenged patents. *Hikma Pharms. USA Inc.*, 449 F. Supp. 3d at 1009–10. Specifically, Judge Du held that REDUCE-It's results turned on administering a statin along with Vascepa, unlike Vascepa that "can be, and often is, used without a statin"; the "benefits in REDUCE-IT, however, were unrelated to reducing triglycerides," which was the target of the challenged patents; REDUCE-IT does not avoid increasing LDL-C, which is part of the "claimed method of avoiding an increase in LDL-C" in the challenged patents; the REDUCE-IT Trial's "results were limited to patients with multiple cardiovascular risk factors that the asserted claims do not require"; and REDUCE-IT Trial did not involve patients with triglyceride levels of at least 500 mg/dL, as in the asserted claims. *Id.*

F. INDIVIDUAL DEFENDANTS' PUBLIC STATEMENTS AND AMARIN'S SHARE PRICE

The Amended Complaint alleges that Amarin's executives made material misrepresentations and omissions during the Class Period about Vascepa's patents and expected profitability. The Amended Complaint recites statements made by three Amarin executives (the "Individual Defendants"): John Thero ("Thero"), Amarin's President, Chief Executive Officer, and a director during the Class Period; Michael Kalb ("Kalb"), Amarin's Senior Vice President and Chief Financial Officer during the Class Period; and Joseph Kennedy ("Kennedy"), an Executive Vice President and Amarin's General Counsel during the Class Period. (*Id.* ¶¶ 23–25.) Thero had worked at Amarin since 2009, Kennedy since 2011, and Kalb since 2016. (*Id.*) The Class Period ran from September 24, 2018—the day Amarin announced the positive REDUCE-IT results—to April 12, 2021—the day Thero retired. (*Id.* ¶ 1.)

1. Defendants' Statements Regarding Amarin's Patents and Vascepa's Uniqueness

The Amended Complaint groups the Individual Defendants' statements into three categories.[4] One set of statements deals with the strength of Amarin's patents and the Nevada Litigation. The Amended Complaint quotes Defendants' statements about the Vascepa patents from healthcare conferences, investor calls, and SEC filings. (*Id.* ¶¶ 138–53.) These include statements made during the initial phases of the Nevada litigation, such as Kennedy's statement on a November 2018 earnings call that while the litigation was in its "early stages," the District Court's *Markman* ruling went "favorably" for Amarin, (*id.* ¶ 138); statements made after Judge Du's unfavorable March 2020 decision, such as Thero's statement on an April 2020 earnings call

[4] The Court does not re-print the entirety of the statements quoted in the Amended Complaint in the Background section, as such statements contained in block quotes are alleged in fifty paragraphs that span over thirty pages of the Amended Complaint. (Am. Compl. ¶¶ 99–153.) Defendants' specific statements are quoted and discussed at length in the Discussion section.

that "[w]e believe that we have numerous arguments that will contribute to a strong substantive appeal," (*id.* ¶ 147); and statements made after the Federal Circuit affirmed Judge Du's decision, such as Thero's statement on a November 2020 earnings call that "[w]e believe that courts were wrong in their decisions, and we will continue to pursue this matter, although we cannot provide any guarantee of success in this pursuit," (*id.* ¶ 153).

Plaintiffs allege that these statements were materially false and misleading because they failed to mention that Amarin was not entitled to patent protection because it "only received patents for Vascepa because Defendants withheld material information . . . from the USPTO examiner," specifically the Kurabayashi Study. (*Id.* ¶ 154.) Therefore, Defendants knew or recklessly disregarded the fact that "Amarin would not succeed in its litigation . . . or any appeals." (*Id.*)

A second set of statements alleged are those regarding Vascepa's "unique" characteristics, which were made at healthcare conferences, on investor calls, and in SEC filings. (*Id.* ¶¶ 99–110.) For example, Thero stated on an earnings call in November 2018 that "[w]e continue to reinforce that REDUCE-IT results are unique to Vascepa." (*Id.* ¶ 101.) On a February 2020 earnings call, again talking about the REDUCE-IT results, Thero said that "Vascepa is the first and only drug with this new cardiovascular risk reduction indication." (*Id.* ¶ 109.) Plaintiffs allege that Defendants made material misstatements as "Vascepa was not unique, and Amarin did not invent purified EPA or discover any of its medical characteristics," because the relevant characteristics had already been attributed to Epadel. (*Id.* ¶ 111.) Plaintiffs again conclude that Amarin was not entitled to its Vascepa patents and only received patents because it "withheld" the Kurabayashi Study. (*Id.*)

2. Market Reaction to the REDUCE-IT Trial and Defendants' Statements Regarding the REDUCE-IT Results

Plaintiffs allege that despite its misrepresentations about Vascepa's uniqueness and the strength of its patents, Defendants created an "inflated impression of Vascepa's prospects" through announcing the REDUCE-IT Trial results. (*Id.* ¶¶ 81–82.) Before the trial's results were announced, Thero stated that "positive REDUCE-IT results would mean that a daily dose of Vascepa would be appropriate treatment for everyone with elevated triglycerides, which comprises 'roughly 1 in 4 adults in the United States.'" (*Id.* ¶ 78 (citation not provided).) This would exponentially increase the potential market for Vascepa. (*Id.*) In this way, Defendants "conditioned the market to believe positive results" in the REDUCE-IT Trial would be, in Thero's words, a "multibillion dollar opportunity" for Amarin. (*Id.* ¶ 84.) In short, Plaintiffs essentially allege that Defendants used the results of the REDUCE-IT Trial to turbocharge market expectations about their unique, patented drug.

After Amarin announced the REDUCE-IT results in September 2018, the "corresponding share price movement was instant and dramatic," jumping from $2.99 per share on the prior trading day to $12.40 per share the day results were announced. (*Id.* ¶ 86.) Analysts attributed this spike to optimism from "the REDUCE-IT results and investors' belief about what those results meant for Vascepa's prospects." (*Id.* ¶ 87.)

In the third category of Defendants' statements cited in the Amended Complaint, Defendants talked about Vascepa's potential market size and value to the company based on the REDUCE-IT results. (*Id.* ¶¶ 112–37.) On the day Amarin announced the REDUCE-IT results, Thero stated on a call that the study showed Vascepa "has the potential to overcome the limitations of multiple blockbuster prior-generation therapies. It thus has the potential to be a significant blockbuster and help millions of patients reduce cardiovascular risk on top of standard-of-care

statin therapy." (*Id.* ¶ 113.) As with the previous categories of statements, the Amended Complaint alleges that these statements were false or misleading because Amarin "did not invent purified EPA or any new use for it," Amarin was not entitled to patent protection for Vascepa, Amarin only received patents because it "withheld" the Kurabayashi Study from the USPTO, and Amarin would not succeed in the Nevada Litigation. (*Id.* ¶ 154.)

3. Individual Defendants' Sale of Amarin Stock

Plaintiffs allege that Defendants' knowledge of the weakness of the Vascepa patents is evidenced by the fact that the Individual Defendants "systematically unloaded their personal shares" of Amarin after the REDUCE-IT results were announced. (*Id.* ¶ 11.) After the results were announced but before Judge Du's decision in March 2020, Kennedy sold 89.19% of his shares of Amarin stock worth $36,504,087; Kalb sold 65% of his shares worth $9,779,380; and Thero sold 24% of his shares worth $36,790,688. (*Id.* ¶¶ 95–97, 170–77.) Several million dollars' worth of Kennedy's and Kalb's sales were made on the day the REDUCE-IT results were announced. (*Id.* ¶ 88.) Plaintiffs allege that "Defendants would not have dumped such large portions of their holdings if they truly believed Vascepa would grow to be a 'multiple-billion-dollar opportunity' as they had led investors to believe." (*Id.* ¶ 12.)

4. Market Reaction to the Patent Litigation

Plaintiffs allege Amarin's share price "came crashing back to reality over the course of three disclosures in 2020 and 2021." (*Id.* ¶ 14.) First, after Judge Du invalidated the Vascepa patents in March 2020, Amarin's ADS price "plummeted by more than 70% to close at $4.00 per share" the following day. (*Id.* ¶ 184; *see also id.* ¶¶ 185–90.) Second, the day after the Federal Circuit affirmed Judge Du's decision in September 2020, Amarin's ADS price again "fell 40.77% to close at $4.30 per share." (*Id.* ¶ 191.) Third, Thero "suddenly" left Amarin "under suspicious

circumstances" on April 12, 2021, which Plaintiffs allege "reveal[ed] to investors he had been culpable for the Company's downfall, and that the Company had given up on recovering its U.S. patents for Vascepa." (*Id.* ¶ 14.) The Amended Complaint elaborates that Thero being replaced with an executive from Merck was a "strong indicator[] that the Company and its senior management believed Thero was to blame for the dramatic decline in the value of the Company." (*Id.* ¶ 178.) Kennedy retired from the company several weeks later as well. (*Id.* ¶ 179.) After the announcement of Thero's retirement, Amarin's ADS price "fell by approximately 13.01% to close at $5.08 per share." (*Id.* ¶ 195.)

G. PROCEDURAL HISTORY [5]

After separate plaintiffs filed complaints bringing similar claims against Amarin, Thero, and Kalb in late 2021, (Civ. Action No. 21-19212 (D.N.J.); Civ. Action No. 21-19911 (D.N.J.)), on October 27, 2022, the Honorable Georgette Castner, U.S.D.J. issued an Order consolidating the

[5] The Court remarks briefly upon two prior unsuccessful securities class actions filed against Amarin over Vascepa, although neither exerts any preclusive effect. They are mentioned merely for context and because Defendants' briefing discusses them.

The first securities class action, filed in this District in 2013, alleged that Amarin and several of its executives made material misrepresentations from 2010 to 2013 about "the progress of Amarin's ultimately unsuccessful application to the FDA to approve its drug, Vascepa, for the treatment of patients with high triglyceride levels." *In re Amarin Corp. PLC Sec. Litig.* (*Amarin I*), No. 13-6663, 2016 WL 1644623, at *1–2 (D.N.J. Apr. 26, 2016). The Honorable Freda L. Wolfson, U.S.D.J. (ret.) dismissed the complaint twice, first in 2015 because the plaintiffs failed to allege that the defendants made materially false or misleading statements or that the defendants acted with scienter. *Id.* *4 (discussing prior decision). The following year, Judge Wolfson again held that the plaintiffs had failed to plead existence of a materially false or misleading statement. *Id.* at *20. On appeal, the Third Circuit affirmed. 689 F. App'x 124 (3d Cir. 2017).

In the second case, filed in 2019 in this District, the plaintiffs sued Amarin and several of its officers alleging that the defendants made material misrepresentations and omissions about the execution and results of the REDUCE-IT Trial and a second trial (the ANCHOR trial). *In re Amarin Corp. PLC Sec. Litig.* (*Amarin II*), No. 19-6601, 2021 WL 1171669, at *1–3 (D.N.J. Mar. 29, 2021). As with the instant action, the class period allegedly began when Amarin announced the results of the REDUCE-IT Trial in September 2018. *Id.* at *2. The plaintiffs alleged that the defendants announced positive results from the REDUCE-IT Trial without disclosing several potential issues with the trial data. *Id.* at *2–3. The Honorable Brian R. Martinotti, U.S.D.J., dismissed the complaint for failure to state a claim for securities fraud, *id.* at *11–19, and the Third Circuit affirmed, No. 21-2071, 2022 WL 2128560 (3d Cir. June 14, 2022).

two matters and appointing the lead counsel and a lead plaintiff in the consolidated action. (ECF Nos. 34, 35.)

Plaintiffs filed the operative 114-page Amended Consolidated Class Action Complaint on January 13, 2023 on behalf of any purchaser of Amarin ADSs during the Class Period. Against all Defendants, the Amended Complaint alleges violations of Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. § 78j(b) and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5 ("Rule 10b-5"). (Am. Compl. ¶¶ 211–18.) Against the Individual Defendants, the Amended Complaint alleges violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), (*id.* ¶¶ 219–24), and Section 20A of the Exchange Act, 15 U.S.C. § 78t-1, (*id.* ¶¶ 225–32).

On March 24, 2023, Defendants filed the Motion to Dismiss at issue here. (ECF No. 58.) Defendants' Motion is supported by a brief, (ECF No. 58-1), and 117 exhibits comprising approximately 1,200 pages, (ECF Nos. 58-2 to -125). Plaintiffs filed a brief opposing the Motion, (ECF No. 65), and separately filed an Objection to Documents that May Be Judicially Noticed in response to Defendants' 117 exhibits ("Plaintiffs' Objection"), (ECF No. 66). Defendants filed a reply brief on the merits of their Motion, (ECF No. 69), and separately responded to Plaintiffs' Objection, (ECF No. 70). Plaintiffs filed a reply supporting Plaintiffs' Objection, (ECF No. 71), which Defendants objected to as an impermissible sur-reply, (ECF No. 72).

II. LEGAL STANDARD

Pursuant to Federal Rule of Civil Procedure 12(b)(6), the court may dismiss a complaint for "failure to state a claim upon which relief can be granted." For a complaint to survive dismissal under this rule, it "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). In evaluating the sufficiency of a complaint, "[a]ll

allegations in the complaint must be accepted as true, and the plaintiff must be given the benefit of every favorable inference to be drawn therefrom." *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011) (citation omitted). A pleading that "offers labels and conclusions," "a formulistic recitation of the elements," or "naked assertion[s] devoid of further factual enhancement," is insufficient. *Iqbal*, 556 U.S. at 678 (citations and quotation marks omitted). In short, the pleading's "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555 (citation omitted).

For fraud claims, a complaint is subject to Rule 9(b)'s heightened pleading standard "[i]ndependent of the standard applicable to Rule 12(b)(6) motions." *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002). "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). A party alleging fraud must support its allegations with "the who, what, when, where and how of the events at issue." *In re Rockefeller*, 311 F.3d at 216 (citation omitted); *see also Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007) ("[T]he plaintiff must . . . inject precision or some measure of substantiation into a fraud allegation."). Rule 9(b)'s heightened pleading standard "ensure[s] that defendants are placed on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of fraud." *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 645 (3d Cir. 1989) (citations and quotations omitted). The standard is "rigorously applied in securities fraud cases." *Cal. Pub. Emps' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 144 (3d Cir. 2004) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1417 (3d Cir. 1997)).

Plaintiffs alleging securities fraud pursuant to the Exchange Act must also comply with the heightened pleading requirements of the Private Securities Litigation Reform Act ("PSLRA"),

15 U.S.C. § 78u–4, *et seq.* The PSLRA "imposes another layer of factual particularity to allegations of securities fraud." *In re Rockefeller*, 311 F.3d at 217. To allege fraud under the PSLRA, the plaintiff must "state with particularity both the facts constituting the alleged violation, and the facts evidencing scienter, *i.e.*, the defendant's intention 'to deceive, manipulate, or defraud.'" *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007) (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194, and n.12 (1976)).

III. DISCUSSION

Defendants contend that Plaintiffs fail to make out a Section 10(b) claim because the Amended Complaint fails to plead an actionable misstatement or omission, a strong inference of scienter, and loss causation. The Individual Defendants seek dismissal of the Section 20(a) and Section 20A claims based on the failure of Plaintiffs' Section 10(b) claim. Finally, Defendants argue that Drabek should be removed from the case caption. The Court addresses the exhibits appended to Defendants' Motion to Dismiss before reaching the merits of their arguments.

A. JUDICIALLY NOTICEABLE DOCUMENTS

The parties raise a threshold dispute over what documents the Court may consider in connection with deciding the Motion to Dismiss. Defendants submitted 117 exhibits, (Exs. to Decl. of Peter J. Linken, ECF Nos. 58-8 to 58-125), and six annexes, (ECF Nos. 58-2 to 58-7), with their Motion.[6] Plaintiffs concede that the Court may properly consider 59 of the exhibits but contest the remaining 58 exhibits and six annexes. (ECF No. 66 at 2.) Plaintiffs contend that Defendants improperly attempt to frontload factual disputes at this motion to dismiss stage with their exhibits. (*Id.* at 5–18.) Defendants respond that many of the exhibits are integral to the Amended

[6] In this Opinion, all references to "Exhibit" or "Ex." refer to the Exhibits to Peter J. Linken's Declaration.

Complaint's allegations and that Plaintiffs selectively included facts in the Amended Complaint to distort what actually happened as an attempt to make it to discovery. (ECF No. 70 at 1–2.)[7]

While the Court may normally "not consider matters extraneous to the pleadings" at the motion to dismiss stage, it may rely on documents that are "*integral to or explicitly relied* upon in the complaint" without converting the motion into one for summary judgment. *See In re Burlington Coat*, 114 F.3d at 1426 (emphasis in original) (citations omitted). The exception's applicability turns on "whether the claims in the complaint are 'based' on an extrinsic document and not merely whether the extrinsic document was explicitly cited." *Id.* at 1426 (citations omitted). The exception's purpose is to prevent a plaintiff from "maintain[ing] a claim of fraud by extracting an isolated statement from a document and placing it in the complaint, even though if the statement were examined in the full context of the document, it would be clear that the statement was not fraudulent." *Id.* at 1426 (citation omitted).

Under Federal Rule of Evidence 201(b), the Court may also consider documents containing facts that are "not subject to reasonable dispute in that [they are] either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." *In re NAHC, Inc. Secs. Litig.*, 306 F.3d 1314, 1331 (3d Cir. 2002) (citing Fed. R. Evid. 201(b)). However, it "is improper for a court to take judicial notice of the veracity and validity of a public document's contents when the parties dispute the meaning and truth of the contents." *Amarin II*, 2021 WL 1171669, at *7 (quoting *Lee v. City of L.A.*, 250 F.3d 668, 690 (9th Cir. 2001)). As the Third Circuit cautioned, "[o]nly in the clearest of cases should a district court reach outside the pleadings for facts necessary

[7] The parties accuse each other of violating procedural rules in connection with Defendants' submission of exhibits and Plaintiffs' objection thereto. (ECF No. 66 at 1–2; ECF No. 70 at 2 n.1; ECF No. 72.) The Court will consider Plaintiffs' Objection, (ECF No. 66), and Defendants' response, (ECF No. 70), but will disregard Plaintiffs' July 20, 2023 brief, (ECF No. 71), as an unauthorized sur-reply.

to resolve a case" at the motion to dismiss stage. *Victaulic Co. v. Tieman*, 499 F.3d 227, 236 (3d Cir. 2007), as amended (Nov. 20, 2007).

Defendants' exhibits fall into several categories, summarized below:

1. **Amarin's SEC filings (Exs. 32 to 65).** Plaintiffs challenge Exs. 32–50 but not Exs. 51–65.
2. **Documents from the patent application before the USPTO (Exs. 66 to 92).** Plaintiffs challenge Exs. 68–72, 75–78, 80–81, 83, 88, 92 but not Exs. 66–67, 73–74, 79, 82, 84–87, 89–91.
3. **Documents from the Nevada Litigation (Exs. 93–94).** Plaintiffs challenge these two exhibits.
4. **Analyst reports (Exs. 95–109).** Plaintiffs challenge these fifteen exhibits.
5. **Kurabayashi Study (Ex. 110).** Plaintiffs challenge this exhibit.
6. **Individual Defendants' Rule 10b5-1 trading plans (Exs. 111–117).** Plaintiffs challenges these seven exhibits.
7. **Annexes. (ECF Nos. 58-2 to -7).** Plaintiffs challenge these documents.
8. **Defendants' Statements referenced in the Amended Complaint. (Exs. 1 to 31).** Plaintiffs do not challenge these documents.[8]

Except for the documents containing statements challenged in the Amended Complaint, which Plaintiffs do not contest the Court may consider, the Court briefly discusses each category.

1. Amarin's SEC Filings

Of the SEC filings included with the Motion to Dismiss, Plaintiffs contest consideration of Exhibits 32 to 50, which are filings from as early as March 2011 (Ex. 32) to August 2018 (Ex. 50). Plaintiffs argue that because these filings were made outside the Class Period, the risk disclosures they contain "cannot cure" the alleged omissions from the Class Period. (ECF No. 66 at 5–6.) The Third Circuit instructs that "[p]re-class period statements may be used to ascertain the falsity and

[8] Plaintiffs caveat their agreement that while certain documents are permissibly considered at this posture such documents may not be "utilized for the truth of the matters asserted to factually argue against Plaintiffs' well-pled allegations of fraud." (ECF No. 66 at 4–5.) To the extent the Court cites these documents below, it will address the purpose for which it relies on them.

materiality of the challenged statements." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 171 n.13 (3d Cir. 2014) (citing *In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 272 (3d Cir. 2005)). Here, the Amended Complaint heavily discusses Defendants' conduct from 2010 to 2018 to support its allegations that Defendants' statements during the Class Period were misleading. (Am. Compl. ¶¶ 51–76.) These disclosures are relevant, and the Court may indisputably take judicial notice of the challenged SEC filings for the purpose of establishing that the disclosures they contained were publicly available. *See In re NAHC*, 306 F.3d at 1331.

2. USPTO Patent Prosecution

Defendants submit twenty-seven documents from Amarin's MARINE patent prosecution proceedings. (Exs. 66–92.) Plaintiffs object to the Court's consideration of fifteen of the documents, (Exs. 68–72, 75–78, 80–81, 83, 88, 92), because they are not referenced in the Amended Complaint. (ECF No. 66 at 6–8.) Plaintiffs do not contest Defendants' claim that each of the challenged documents is publicly available on the USPTO's website. (Decl. of Peter J. Linken ¶¶ 68–94, ECF No. 58-8.) Here, the Amended Complaint extensively discusses and quotes from the proceedings before the USPTO, including Amarin's two Form PTO-1449 (the second of which included the Kurabayashi Study), the examiner's four rejections of Amarin's application, and Amarin's multiple submissions to the examiner in response. (Am. Compl. ¶¶ 53–72.) Therefore, the documents from the patent prosecution history are appropriately considered both because they are integral to the Amended Complaint's claim that Defendants "concealed" the Kurabayashi Study from the USPTO and because they are subject to judicial notice. *See Lexington Luminance LLC v. Bulbrite Indus., Inc.*, No. 22-3787, 2023 WL 143911, at *1 (D.N.J. Jan. 10, 2023) (taking judicial notice of public records from the USPTO's website); *Genetic Techs. Ltd. v.*

Bristol-Myers Squibb Co., 72 F. Supp. 3d 521, 526 (D. Del. 2014) (same), *aff'd*, 818 F.3d 1369 (Fed. Cir. 2016).

3. Documents from the Nevada Litigation

Plaintiffs object to consideration of the two documents from the Nevada Litigation, (Exs. 93–94), arguing that Defendants use these documents "to make inappropriate merits-based arguments and factual assertions." (ECF No. 66 at 8.) A review of Defendants' brief shows that Exhibit 94 is not mentioned in the argument at all and Exhibit 93 is only mentioned in a final footnote listing arguments *not* made. (ECF No. 58-1 at 65 n.61.) Therefore, the Court need not consider these documents.

4. Analyst Reports

Defendants submitted fifteen publicly-available reports from market analysts regarding the status of the Nevada litigation and the analysts' investment recommendations on Amarin. (Exs. 95–109.) Plaintiffs object to their consideration, contending that Defendants offer them to show "that Amarin indeed had strong [intellectual property] and therefore Defendants reasonably believed it [sic] would prevail in the patent litigation." (ECF No. 66 at 11–12.) Defendants respond that they cite the reports "to show that Defendants (and the public) would have been aware that other experts expressed agreement with Amarin's litigation position and disclosed their views that the MARINE patents were valid." (ECF No. 70 at 14.) Here, contrary to Defendants' assertions, Defendants appear to rely on these documents for the truth of the analysts' statements that Amarin's litigation position was strong and that Individual Defendants' statements about the litigation were reasonable. (*See* ECF No. 58-1 at 35–36.) The Court therefore will not consider these reports for the purpose for which Defendants offer them. *See In re PTC Therapeutics, Inc. Sec. Litig.*, No. 16–1124, 2017 WL 3705801, at *3 n.5 (D.N.J. Aug. 28, 2017) ("[T]he inferences

defendants wish to draw from these [analyst reports] go beyond the mere existence of statements within them").

5. Kurabayashi Study

Plaintiffs object to the Court's consideration of the Kurabayashi Study, (Ex. 110), essentially arguing that Defendants seek to contradict the results of the Nevada Litigation through discussion of the Kurabayashi Study. (ECF No. 66 at 9–10.) Defendants counter that the Kurabayashi study is the "cornerstone of Plaintiffs' claims" and is mentioned in the Amended Complaint almost thirty times. (ECF No. 70 at 9–10.) The Court will consider the Kurabayashi Study because it is plainly integral to the Amended Complaint. Plaintiffs' claims are premised on Defendants' alleged conduct with respect to the Kurabayashi Study, namely that Defendants "concealed the Kurabayashi Study from the USPTO by burying it amongst hundreds of other studies provided to the patent examiner," (Am. Compl. ¶ 7), and then failing to disclose this vulnerability in Amarin's patent to the investing public.[9]

6. Rule 10b5-1 Trading Plans

Defendants submitted excerpts from the Individual Defendants' Rule 10b5-1 pre-arranged trading plans adopted by Kalb and Kennedy at various dates in 2017 and 2018. (Exs. 111–17.) As Judge Wolfson explained generally, "[a] Rule 10b5-1 plan is a written plan that allows corporate insiders to make prearranged stock transactions." *In re Synchronoss Techs., Inc. Sec. Litig.*, No. 17-2978, 2019 WL 2849933, at *5 (D.N.J. July 2, 2019) (citing 17 C.F.R. § 240.10b5-1(c)). Plaintiffs object that these are internal company documents, not publicly available, whose

[9] Judge Wolfson's decision in *Hall v. Johnson & Johnson*, No. 18-1833, 2019 WL 7207491 (D.N.J. Dec. 27, 2019), is not to the contrary. There, the Court declined to consider a scientific study that "addresses the merits of Plaintiff's claims, is not relied upon or integral to the Complaint, and would require the court to delve into the scientific evidence that forms the crux of the parties' dispute." *Id.* at *11. In *Hall*, the contested exhibit was an outside study defendants brought into the case in their motion to dismiss, rather than a study treated at length in the plaintiffs' pleading whose alleged concealment was central to the case.

authenticity cannot be determined. (ECF No. 66 at 12–13.) Defendants respond that courts routinely consider pre-arranged trading plans at the motion to dismiss stage. (ECF No. 58-1 at 52–53; ECF No. 70 at 15, 15 n.20 (collecting cases).) Defendants contend that the Individual Defendants' Form 4s SEC filings—which Defendants also submit with their Motion, (Exs. 63–65), and to which Plaintiffs do not object, (ECF No. 66 at 2)—by themselves are sufficient "to defeat any inference of 'suspicious' sales here." (ECF No. 70 at 15.) Defendants claim that they only provided the Rule 10b5-1 plans themselves for the limited purpose of documenting the plans' entry dates, set windows, amounts, and trigger prices. (*Id.*)

The Court finds that it may not take judicial notice of the Rule 10b5-1 trading plans. As explained in the scienter section below, courts in the Third Circuit regularly consider Form 4s to assess insider trading allegations on motions to dismiss. *See Amarin II*, 2021 WL 1171669, at *9 (collecting cases). The Individual Defendants' Form 4s are publicly filed, and Plaintiffs therefore concede they are appropriately considered. However, while the Form 4s are public records, Defendants do not suggest that the Rule 10b5-1 plans are. Instead, Defendants essentially argue that because the Form 4s reference the Rule 10b5-1 plans, the latter may be judicially noticed, despite the fact that it is not publicly filed. None of the cases Defendants cite to support this proposition. As the Third Circuit explained regarding Form 4s, the Court may "take judicial notice of properly-authenticated public disclosure documents filed with the SEC." *Oran v. Stafford*, 226 F.3d 275, 289 (3d Cir. 2000). Judicial notice under Rule 201 is appropriate because "the documents are required by law to be filed with the SEC, and no serious questions as to their authenticity can exist." *Id.* (quoting *Kramer v. Time Warner Inc.*, 937 F.2d 767, 774 (2d Cir. 1991)). Because

Defendants offer no authority suggesting that a document not publicly filed and not relied on in the Amended Complaint can be judicially noticed, the Court will not do so here.[10]

7. Annexes

Defendants submitted six annexes with their opposition brief.[11] Plaintiffs argue that the annexes are "lawyer-created documents," "neither judicially noticeable nor relied upon by the Complaint," and offered to get around Defendants' 65-page brief limit. (ECF No. 66 at 14–15.) Plaintiffs also object that several of the charts "employ[] a system designed to be confusing," several other annexes contain data that "ha[s] no relevance to this litigation" and "alternative calculations" that rebut the Amended Complaint's allegations. (*Id.* at 15–17.) Defendants respond that the annexes are permissible "organizational tools" rather than legal argument. (ECF No. 70 at 16–17.)

The Court will not strike Annexes A, B, and C because they are permissible organizational tools. *See In re PTC Therapeutics, Inc. Sec. Litig.*, 2017 WL 3705801, at *3. Given the volume of statements relevant to this case by virtue of their inclusion in the Amended Complaint, Defendants' attempt to organize their arguments that apply to some statements but not others is well taken. In contrast, Annexes D, E, and F contain information either not derived from exhibits Defendants

[10] While Defendants cite several cases in which Courts have relied on Rule 10b5-1 plans directly, the plans in those cases appear to have been directly filed with the SEC. *See, e.g.*, *In re Synchronoss Techs., Inc. Sec. Litig.*, No. 17-2978, 2019 WL 2849933, at *16 n.11 (D.N.J. July 2, 2019) (considering Rule 10b5-1 plans "because they are publicly-filed SEC documents").

[11] Annexes A, B, and C contain charts listing which of Defendants' alleged statements Defendants argue are not actionable misstatement or omissions: Annex A lists "forward-looking statements" accompanied by cautionary language; Annex B lists statements that are puffery; and Annex C lists "statements of historical fact." Annex D contains three charts of Amarin's historical stock price and Thero's and Kennedy's challenged stock sales. Annex E contains charts showing Defendants' calculations of the Individual Defendants' stock holdings (which Defendants contend differ from the Amended Complaints). Annex F contains charts matching each of the Individual Defendants stock sales to the exhibit of their Form 4 or Rule 10b5-1 Plan that shows the sale was pre-arranged.

submitted or derived from exhibits the Court cannot consider at this juncture. Therefore, the Court will not consider them.

* * *

In summary, in deciding Defendants' Motion to Dismiss, the Court will consider: documents containing Defendants' Statements referenced in the Amended Complaint, (Exs. 1 to 31); Amarin's SEC filings, (Exs. 32 to 65); documents from the patent application before the USPTO, (Exs. 66 to 92); the Kurabayashi Study, (Ex. 110); and Annexes A, B, and C, (ECF Nos. 58-2 to -4). However, the Court will not consider: the two documents from the Nevada Litigation, (Exs. 93–94); the market analyst reports, (Exs. 95–109); the Individual Defendants' Rule 10b5-1 trading plans, (Exs. 111–17); and Annexes D, E, and F, (ECF Nos. 58-5 to -7).

B. MOTION TO DISMISS SECTION 10(B) CLAIM

Section 10(b) of the Exchange Act creates a private cause of action for the "use or employ, in connection with the purchase or sale of any security . . . [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). SEC Rule 10b-5, which implements Section 10(b), makes it unlawful, in connection with the purchase or sale of any security:

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person.

17 C.F.R. § 240.10b-5. To survive a motion to dismiss, a plaintiff bringing a claim under Section 10(b) and Rule 10b-5 must allege: "(1) a material misrepresentation or omission by the

defendant; (2) scienter; (3) a connection between the misrepresentations or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) and causation." *Stoneridge Inv. Partners, LLC v. Sci.-Atlanta*, 552 U.S. 148, 157 (2008) (citing *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341–42 (2005)). In a securities fraud case, "[a] corporation is liable for statements by employees who have apparent authority to make them." *Inst. Invs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009) (citing *Makor Issues & Rights, Ltd. v. Tellabs Inc.*, 513 F.3d 702, 708 (7th Cir. 2008)).

1. Actionable Misstatement or Omission

The Court begins with Defendants' argument that the Amended Complaint does not allege an actionable material misrepresentation or omission. Plaintiffs' claims are based on statements about Vascepa made over a two-and-a-half year period, set out in detailed block quotes alleged in fifty paragraphs over thirty pages of the Amended Complaint. (Am. Compl. ¶¶ 99–153.) Within the quotations, Plaintiffs highlight certain language. Plaintiffs do not specify how any specific statement is allegedly false or misleading. Instead, Plaintiffs group the statements into three sections and at the end of each section, generally allege how those statements are misleading. (*Id.* ¶¶ 111, 137, 154.) Defendants mirror this approach, addressing Plaintiffs' arguments within each of the three categories. (ECF No. 58-1 at 34–48.) The Court will not examine each statement individually, but rather, consistent with the parties' approach, will assess each category of allegedly false and misleading statements and identify specific statements as examples, where necessary.

To make out a Section 10(b) claim, a plaintiff must adequately allege that the defendant made "a material misrepresentation or omission." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 167 (3d Cir. 2014) (citing *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37

(2011)). A statement or omission of fact is material if there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988) (citation omitted); *see also In re Newell Brands, Inc. Sec. Litig.*, 837 F. App'x 869, 874 (3d Cir. 2020) (statements or omissions viewed "in light of all the information then available to the market" (citation omitted)). Further, a statement or omission only gives rise to liability if it was "misleading at the time it was made; liability cannot be imposed on the basis of subsequent events." *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1330 (3d Cir. 2002).

This element is subject to the PSLRA's "[e]xacting pleading requirements." *City of Edinburgh*, 754 F.3d at 168 (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007)). Thus, "[a] complaint involving securities fraud must 'specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation . . . is made on information and belief . . . all facts on which that belief is formed.'" *In re Newell Brands.*, 837 F. App'x at 874 (quoting 15 U.S.C. § 78u-4(b)(1)). "The purpose of the heightened pleading requirements is to ensure that private securities actions do not become 'a partial downside insurance policy' against the vicissitudes of the market." *Id.* at 874 (quoting *City of Cambridge Ret. Sys. v. Altisource Asset Mgmt. Corp*, 908 F.3d 872, 800 (3d Cir. 2018)).

The contours of what qualifies as an actionable misstatement are well articulated. An opinion is actionable under the securities laws if it "(i) was not sincerely believed when made; (ii) contains an expressly embedded, untrue factual assertion; or (iii) reasonably implies untrue facts and omits appropriate qualifying language." *City of Warren Police & Fire Ret. Sys. v. Prudential Fin., Inc.*, 70 F.4th 668, 686 (3d Cir. 2023) (citing *Omnicare, Inc. v. Laborers Dist.*

Council Const. Indus. Pension Fund, 575 U.S. 175 (2015)).[12] Next, the PSLRA creates a "safe harbor" for forward-looking statements. Alleged misrepresentations are not actionable if the statements "are (1) identified as [forward-looking], and accompanied by meaningful cautionary statements; or (2) immaterial; or (3) made without actual knowledge that the statement was false or misleading." *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 278 (3d Cir. 2010) (citing 15 U.S.C. § 78u-5(c)). Finally, the Court must distinguish material representations from statements that "constitute no more than 'puffery' and are understood by reasonable investors as such." *In re Newell Brands*, 837 F. App'x at 874 (quoting *EP Medsystems, Inc. v. EchoCath, Inc.*, 235 F.3d 865, 872 (3d Cir. 2000)).

The Amended Complaint identifies three categories of purported actionable misstatements or omissions, made in connection with (1) the Nevada Litigation, (2) Vascepa's "unique" characteristics, and (3) Amarin's financial prospects based on the release of the REDUCE-IT Trial results. (Am. Compl. ¶¶ 99–154.) Defendants contend that Plaintiffs fail to plead an actionable misstatement or omission with respect to each category. The Court addresses each in turn.

i. MARINE Patent Litigation

The Amended Complaint cites sixteen instances in which Individual Defendants made allegedly false and misleading statements relating to their expectation of the outcome of the patent litigation. (Am. Compl. ¶¶ 138–53.) Plaintiffs allege that these statements are materially false or misleading because they failed to disclose that (1) Amarin did not invent purified EPA or any use

[12] Although the parties' briefing, filed before the Third Circuit in *City of Warren* confirmed that *Omnicare*'s framework for opinion liability applies to Section 10(b) claims, applying *Omnicare* does not change their arguments. As the Third Circuit explained, this Circuit had "prefigured the *Omnicare* framework in imposing liability for opinions 'issued without a genuine belief or reasonable basis.'" *City of Warren Police*, 70 F.4th at 686 (quoting *In re Merck & Co., Inc. Sec., Derivative & "ERISA" Litig.*, 543 F.3d 150, 166 (3d Cir. 2008)). Thus, the three-part *Omnicare* framework is merely a "more developed articulation" of the Third Circuit's prior test, and the Court's conclusion here does not change whether it applies *In re Merck*'s articulation or *Omnicare*'s.

for it, (2) Amarin concealed the Kurabayashi Study from the USPTO, and (3) Amarin was not entitled to patent protection for Vascepa and would ultimately lose the patent litigation. (*Id.* ¶ 154.)

Defendants argue that Plaintiffs have not alleged any actionable statements regarding the patent litigation. First, Defendants contend that the Individual Defendants' statements regarding their belief that the MARINE patents would be upheld are inactionable opinions. (ECF No. 58-1 at 34.) Plaintiffs failed to allege that Defendants lacked a reasonable basis for their opinions, despite the fact that Amarin was ultimately unsuccessful in defending its patents. (*Id.* at 34–36.) Defendants argue that Plaintiffs' claim that they "concealed" the Kurabayashi Study by filing it with their Form 1449 is unsupported. (*Id.* at 38–39.) Further, Defendants also point out that their statements about the litigation were repeatedly tempered by warnings about the possibility the patents would be invalidated. (*Id.* at 36–37.) Defendants' also contend that several of their statements about the litigation were forward-looking statements protected by the PSLRA's safe harbor or constituting inactionable puffery. (*Id.* at 40–42.)

Plaintiffs respond that Defendants' rosy statements about the litigation were not inactionable opinions because they lacked a "reasonable basis." (ECF No. 65 at 34.) Plaintiffs contend that Defendants ignore the Amended Complaint's allegations that Vascepa's patents were invalid because Amarin misled the USPTO. (*Id.* at 35.) Plaintiffs argue that Defendants' "generic disclosure buried in Amarin's quarterly SEC filings" are insufficient to render their omissions inactionable. (*Id.* at 36.) Plaintiffs argue that the PSLRA safe harbor is unavailable because the statements about the litigation's outcome were made with knowledge they were misleading. (*Id.* at 37–38.)

The Court agrees with Defendants that the Amended Complaint fails to allege any actionable misstatements or omissions about the Nevada Litigation. First, the fourteen challenged

statements in this section are plainly opinions. Describing the litigation before Judge Du's March 2020 decision, Defendants' statements characterized different stages of the litigation—after the ANDAs were filed, after the *Markman* ruling, and after summary judgment—as going "very favorably" for Amarin. (Am. Compl. ¶¶ 138–46.)[13] After Judge Du's unfavorable decision and ahead of the Federal Circuit's affirmance, Defendants continued to make statements expressing optimism in the "strong substantive appeal" it could make. (*Id.* ¶ 147–51.)[14] After the Federal

[13] (*See* Am. Compl. ¶ 138 (describing the court's *Markman* ruling was going "very favorably" for Amarin and that the company "feel[s] pretty good about that"); *id.* ¶ 139 ("Any good product gets ANDA filers. It'd be almost insulting if they weren't, I guess. . . . I think the results coming out of that claims construction was very favorable to us. . . . [T]hese patents were heavily prosecuted through the U.S. Patent Office and as I say, we intend to defend them vigorously."); *id.* ¶ 140 ("So being able to show something different for that was deemed to be unique and the ANDA filers have acknowledged that where they'd have generic product that they would infringe that patent . . ."); *id.* ¶ 141 ("Our patents expire in 2030. . . . We continue to defend our patents vigorously."); *id.* ¶ 142 ("This is a global epidemic, and this is – we have global rights to the product, and we feel like we're just getting started. . . . [Our patents] all have expiries in 2030. They all have multiple claims, and we intend to defend those patents vigorously. . . . So we'll see what happens relative to the end of litigation. I can't make any predictions there other than stating that we intend to defend our patents vigorously, and we like our IP."); *id.* ¶ 143 ("The judge ruled against the [ANDA] filer's summary judgment motion that sought to end the case at this early stage in their favor . . . . We see this ruling as strengthening our position in the litigation . . . should it be determined that case settlement is in the company's best interest."); *id.* ¶ 144 ("From a data exclusivity perspective, in the United States, we've protected, via patents, 2 different indications. Our initial indication, which is for the trig[lyceride]s greater than 500, is currently subject to ANDA litigation. . . . Obviously we're confident in the results [expected in the litigation], which is why we're expanding our commercial infrastructure."); *id.* ¶ 145 ("[W]e believe that our legal arguments are persuasive and should prevail. The U.S. Patent Office was convinced of the appropriateness of our patents, and we believe that the court should conclude similarly."); *id.* ¶ 146 (describing a recent proceeding in the Nevada litigation as offering no "real negative surprises and an increase in confidence" causing Amarin to "think that we are in a good position based upon our intellectual property").)

[14] (*See* Am. Compl. ¶ 147 ("[W]e were surprised and disappointed that the court determined that patent, upon which we relied to build our business, should be considered invalid based upon arguments of perceived obviousness. In doing so, in my view, the court's decision . . . did not fully appreciate the importance of VASCEPA as a unique and valuable breakthrough therapy, for which I believe there is considerable evidence . . . ."); *id.* (discussing Amarin's "broader belief that our patents should have been upheld as inventive and not obvious."); *id.* ("We believe that we have numerous arguments that will contribute to a strong substantive appeal. Many of you have expressed to us examples of arguments that go to a point that could be argued on appeal."); *id.* ¶ 148 ("Amarin believes that it has a strong basis for appeal, which will be set out in its opening brief . . . ."); *id.* ¶ 149 ("We have filed our appeal to the Federal Circuit. We and our outside counsel believe that we have numerous strong arguments that will contribute to a substantive appeal. . . . [I]t remains stunning that the invention of VASCEPA can now be viewed by anyone as obvious. . . . Amarin is vigorously pursuing this appeal. We are doing so fully convinced that the invention of VASCEPA was not obvious."); *id.* ¶ 150 ("Amarin believes strongly that the lower court

Circuit affirmed, Defendants' statements showed their intent to "vigorously" defend its patents and continue litigating the matter to the Supreme Court. (*Id.* ¶ 152–53.)[15] These statements about the litigation—that Amarin believed that the litigation was going "very favorably," that the patents were "heavily prosecuted" before the USPTO, that Amarin was "vigorously" litigating its claims, that certain rulings "strengthen[ed]" Amarin's position, that's arguments were "persuasive," that the litigation offered no "negative surprises," that Amarin was "disappointed" in Judge Du's decision, that Amarin's "patents should have been upheld," that Amarin had "numerous arguments that will contribute to a strong substantive appeal," that Amarin had a "a reasonable shot at winning"—put forward Amarin's belief about the strength of their patents, rather than asserting positive knowledge of what the outcome of the litigation would be. As Judge Wolfson held in an analogous matter, Defendants' "statements regarding the viability of the lawsuits . . . clearly constitute opinions regarding the success of the litigation, rather than statements of fact." *Hall v. Johnson & Johnson*, No. 18-1833, 2019 WL 7207491, at *19 (D.N.J. Dec. 27, 2019) (citing *Axar Master Fund, Ltd. v. Bedford*, 308 F. Supp. 3d 743, 756-57 (S.D.N.Y. 2018)); *see also Laasko v. Endo Int'l, PLC*, No. 20-7536, 2022 WL 3444038, at *4 (D.N.J. Aug. 17, 2022) (finding no

judgment was seriously flawed and that it has strong arguments on appeal that could result in a victory for Amarin."); *id.* ¶ 151 ("The decision was unexpected by everyone, including, we understand, the generic companies involved in the litigation. As discussed in the past, we believe that the District Court decision is flawed. . . . Unfortunately, the judicial process is such that it doesn't matter that I, you or others conclude that the District Court's decision was wrong. . . . However, while we believe that we have good legal arguments and that our patents should be upheld and that we have a reasonable shot at winning, there is no way for us to guarantee that the Federal Circuit will decide in Amarin's favor. . . . But regarding the patent side, clearly, we think that the right answer here should be that we win and we then have exclusivity until generics could come into the market in 2029. I think that, that is the right answer.").)

[15] (*See* Am. Compl. ¶ 152 ("We believe the key court decisions regarding VASCEPA patents related to the triglyceride lowering indication have been wrong and we plan to continue to pursue this matter to the highest level."); *id.* ¶ 153 ("We believe that courts were wrong in their decisions, and we will continue to pursue this matter, although we cannot provide any guarantee of success in this pursuit.").)

actionable misstatement where plaintiffs alleged that defendants "assured investors they would vigorously contest the merits of the opioid-related actions").

Plaintiffs argue that these opinions are nonetheless actionable because they allege that Defendants made them in bad faith. (ECF No. 65 at 34.) An opinion statement is not actionable unless it "(i) was not sincerely believed when made; (ii) contains an expressly embedded, untrue factual assertion; or (iii) reasonably implies untrue facts and omits appropriate qualifying language." *City of Warren Police*, 70 F.4th at 686. Plaintiffs' primary contention in support of this point is that Defendants could not have honestly believed they would succeed in the Nevada Litigation because they "concealed" the Kurabayashi Study and "misled" the USPTO by doing so. (ECF No. 65 at 34–35.) As alleged in the Amended Complaint, Amarin owed a "duty of candor and good faith in dealing with the [USPTO], which includes a duty to disclose to the [USPTO] all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56. The disclosure duty "is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the [USPTO] or submitted to the [USPTO] in the manner prescribed by §§ 1.97(b)–(d) and 1.98." *Id.* The rule's requirements are not met when "the duty of disclosure was violated through bad faith or intentional misconduct." *Id.*

On its face, the rule simply requires that an applicant disclose relevant information to the examiner. That is exactly what Defendants did by submitting the Kurabayashi Study with their Form 1449. (Am. Compl. ¶ 55.) Plaintiffs fail to allege that Amarin ran afoul of this obligation by submitting the Kurabayashi study as one among several hundred documents filed with the USPTO. While Plaintiffs point to language in the rule saying that it is not met if there is "bad faith or intentional misconduct," 37 C.F.R. § 1.56, they have alleged neither here. As one court explained,

"allegations that the prosecuting attorney attempted to bury the [USPTO] Examiner with less relevant references is not persuasive because disclosure of hundreds of patents and publications is also entirely consistent with the Applicants fulfilling their duty to disclose [under section 1.56]." *Bridgestone Americas Tire Operations, LLC v. Speedways Tyres Ltd.*, No. 22-0145, 2023 WL 5105776, at *3 (N.D. Tex. Aug. 9, 2023).[16]

Plaintiffs point to nothing from the Nevada litigation that would suggest that the patents' invalidation was a foregone conclusion over the six years of litigation. Judge Du merely disagreed with the patent examiner, finding that the Kurabayashi Study suggested that results from the MARINE Trial were not "unexpected benefits." *Amarin Pharma, Inc.*, 449 F. Supp. 3d at 1013. While Judge Du wrote that the USPTO "did not consider" the Kurabayashi Study, Judge Du did not blame Defendants for this. *Id.* Finding Defendants' opinions about the progress of the Nevada Litigation actionable based on the bare fact that Amarin ultimately lost would constitute impermissible "fraud by hindsight." *See In re Amarin Corp. PLC Sec. Litig.*, 689 F. App'x 124, 132 (3d Cir. 2017) (affirming dismissal of securities fraud claims where plaintiffs relied on the fact that the FDA changed its initial belief after receiving new data (quoting *OFI Asset Mgmt. v.*

[16] The Federal Circuit case Plaintiffs cite in support of their argument that Amarin violated its duty to the USPTO does not support its argument. In *Molins Plc v. Textron*, a patent practitioner had previously represented to foreign patent offices that a study was "the closest prior art" but never referenced this "highly material reference" to the USPTO. 48 F.3d 1172, 1181 (Fed. Cir. 1995). The trial court found that when the practitioner's successors found out about the omission when reviewing the file on reexamination, their decision to "bury" the study amid other prior art violated their duty of candor because they had "knowledge of [the predecessor's] actions in the foreign prosecutions." *Id.* at 1183. The Federal Circuit reversed, finding that the trial court erred because "[t]hese circumstances therefore do not present clear and convincing evidence of intent on the part of [the successors] to conceal [the study] from the PTO during the reexamination." *Id.* at 1184.

Even had the Federal Circuit affirmed, the allegations of the Amended Complaint suggesting wrongdoing would fall well below the facts presented in *Molins*. As it is, *Molins* only underscores the point that Plaintiffs have failed to allege that Amarin violated its duty of candor to the USPTO here.

Cooper Tire & Rubber, 834 F.3d 481, 497 (3d Cir. 2016))); *see also In re NAHC*, 306 F.3d at 1330 ("[L]iability cannot be imposed on the basis of subsequent events.").[17]

Although not necessary to the Court's conclusion, a review of the USPTO record—which is a matter of public record and which Plaintiffs and their attorneys surely scoured in drafting the Amended Complaint—further expose the inadequacy of Plaintiffs' allegations. As Plaintiffs note, the patent examiner stamped the references Amarin submitted, including one listing the Kurabayashi Study, with the phrase "ALL REFERENCES CONSIDERED." (Ex. 78.) The examiner's search notes reflect that he searched Amarin's submissions for the word "Epadel," (Ex. 77), which is the drug administered in and discussed by the Kurabayashi Study. In the first rejection of Amarin's patent claim in June 2011, the examiner cited three studies, (Ex. 80), all of which were listed after Kurabayashi on Amarin's Form 1449, (Ex. 74). Plaintiffs fail to allege how, given these strong indications that the examiner reviewed the submitted prior art, including Kurabayashi, Defendants omitted material information by not highlighting the Kurabayashi Study to the investing public. In this light, the Amended Complaint has failed to allege facts supporting its assertion that "Amarin only received patents for Vascepa because Defendants withheld material information concerning the relevant prior art from the USPTO." (Am. Compl. ¶ 154); *see also Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995) (assuming examiner considered references when he "initialed each reference, indicating his consideration of the same, and stated that he had considered all of the cited prior art"). While these documents do not, at this stage of

[17] In fact, the patent's history supports Defendants reasonable belief in their opinions. As Defendants note, receiving the patents granted them a presumption of validity. 35 U.S.C. § 282(a). In a 2018 *Markman* decision, Judge Du adopted Amarin's proposed definition for four of the five disputed terms. *See Amarin Pharma, Inc. v. W.-Ward Pharms. Corp.*, No. 16-2525, 2018 WL 3824348, at *7 (D. Nev. Aug. 10, 2018). In 2019, Judge Du denied-in-part the generic competitors' motion for summary judgment, delivering Amarin a partial win in defense of its patents and permitting the matter to proceed to trial. *See Amarin Pharma, Inc. v. W.-Ward Pharms. Int'l Ltd.*, 407 F. Supp. 3d 1103, 1120 (D. Nev. 2019).

the litigation, show what the patent examiner actually did or did not do, they undermine Plaintiffs' bare allegations of what Defendants knew—*i.e.* their "reasonable basis"—for their in opinions about the litigation.[18]

Plaintiffs contend that it is enough for them to allege that Defendants "knew that 'Amarin's patents were issued in error' and 'Amarin would not succeed in its litigation against the ANDA filers.'" (ECF No. 65 at 34 (quoting Am. Compl. ¶ 154).) However, Plaintiffs must not just allege "actual knowledge" but also "plead with particularity facts that so demonstrate." *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 239 (3d Cir. 2004) Cases in which a complaint adequately alleges no reasonable basis point to a contradiction between the company's internal and public statements to support the claim. *See Hall*, 2019 WL 7207491, at *18 (lack of a reasonable basis found when the complaint cites "defendant's own internal statements [that] undercut their public interpretations of the data available"); *In re Chemours Co. Sec. Litig.*, 587 F. Supp. 3d 143, 159 (D. Del. 2022) (lack of reasonable basis for an opinion that a company's liability may be several hundreds of millions of dollars found when defendants had received an internal, undisclosed report that the liability may be up to two billion dollars). Even "allegations [that] show a difference of opinion within" a company regarding publicly-stated opinions may be insufficient. *See City of Edinburgh*, 754 F.3d at 170. Here, Plaintiffs do allege any confidential witness, internal document, or any other contemporaneous source, *In re Newell Brands*, 837 F. App'x at 875

[18] Again, although not necessary for the Court's decision, a review of the Kurabayashi Study shows differences between it and the MARINE Trial—unacknowledged and unaddressed by the Amended Complaint—that undermine Plaintiffs' allegation that Defendants could not have had a reasonable basis for their opinions. For example, the MARINE Trial was conducted on patients with triglyceride levels of 500 to 2000 mg/dL, (Am. Compl. ¶ 51), and the crux of Amarin's patent based on the MARINE Trial is a treatment for patients with triglyceride levels between 500 and 1,500 mg/dL, (*id.* ¶ 53); in contrast, the Kurabayashi Study's patient population had triglyceride levels of only 150 to 400 mg/dL, (Ex. 110 at 522). The MARINE Trial subjects received only Vascepa (*i.e.* EPA), (Am. Compl. ¶ 51), while the Kurabayashi Study participants received both Epadel (EPA) and estriol, (Ex. 110 at 521).

("Plaintiff's allegations fail to refer to contemporaneous sources showing that Defendants' statements were false or misleading."), showing that anyone within Amarin at any point did not believe in the MARINE patents, let alone specifically that the Kurabayashi Study would have been fatal to their patent had it been considered. Defendants are therefore not "plausibly alleged to have lacked sincerity in making" their statements. *Amaya*, 258 F. Supp. 3d at 468–69.

Finding that these statements did not make an actionable omission is supported by Defendants' contemporaneous, tempering words about their likelihood of success in the litigation. The Court engages in a "full reading" of Defendants' statements "under the PSLRA's heightened pleading requirements," *City of Edinburgh*, 754 F.3d at 169, considering whether Defendants' "use of cautionary language in analyzing whether the plain language of [their public statements] was false or misleading," *id.* at 177 n.16. In the same breath as language Plaintiffs rely on for their claims, Defendants also disclosed the risks inherent in litigation and the potential that the patent would not be successful. For example, at a June 12, 2019 healthcare conference, Thero talked about the litigation but concluded "we'll see what happens relative to the end of litigation. I can't make any predictions there other than stating that we intend to defend our patents vigorously . . . ." (Am. Compl. ¶ 142.)[19] These cautionary statements are not limited to "generic disclosures buried"

[19] (*See also* Am. Compl. ¶ 138 (warning to "just wait until really the second half of [2019]"); *id.* ¶ 145 (acknowledging "risk in any litigation"); *id.* ¶ 146 ("[T]here's risk involved with any ANDA litigation . . . ."); *id.* ¶ 147 (maintaining belief in Amarin's patents after Judge Du's decision but cautioning that the "appeal process likely won't focus on much of the content which I just expressed, and therefore, such arguments matter little"); *id.* ¶ 151 (describing Amarin's intent to and basis for appealing Judge Du's decision but noting that "[u]nfortunately, the judicial process is such that it doesn't matter that I, you or others conclude that the District Court's decision was wrong"); *id* ¶ 152 (acknowledging "there is no way for us to guarantee that the Federal Circuit will decide in Amarin's favor" and that the "Federal Circuit could rule in favor of the generic companies and confirm the District Court decision" because "overturning a lower court ruling has not been easy in the industry historically"); *id.* ¶ 153 (noting that Amarin "cannot provide any guarantee of success in" its appeal to the Supreme Court).)

Before Judge Du's ruling, Thero explicitly contemplated losing the Nevada Litigation, warning that "the court's decision on this matter is expected near the end of March" and that "it would be a considerable setback to pharmaceutical development and patient care if we do not prevail in this litigation." (*Id.* ¶ 145.)

in the company's SEC filings, (ECF No. 65 at 36), but rather follow on the heels of the alleged misstatements from the Amended Complaint.

Defendants' statements also referred investors to their SEC disclosures, such as Thero's statements on a November 5, 2019 earnings call "refer[ring] investors to the court's order and other court documents for further detail." (*Id.* ¶ 143.)[20] "[S]elective statements of optimism concerning [litigation] are generally not misleading when a company also 'explicitly caution[s] investors' that the results of the [litigation] are still uncertain." *Paxton v. Provention Bio, Inc.*, No. 21-11613, 2022 WL 3098236, at *12 (D.N.J. Aug. 4, 2022) (quoting *City of Edinburgh*, 754 F.3d at 168–69). A review of Amarin's SEC filings from well before and into the Class Period offer standard warnings that Amarin may not receive or be able to defend its patents.[21] *In re Amarin Corp. PLC Sec. Litig.*, No. 21-2071, 2022 WL 2128560, at *3 (3d Cir. June 14, 2022) ("We further agree with the District Court that the plaintiffs' theory of omission liability is unpersuasive given Amarin's contemporaneous disclosures [in quarterly and annual SEC filings] regarding the mineral oil placebo.").

Plaintiffs point to cases in which courts have found generic warnings of litigation risk inadequate to cure material omissions. (ECF No. 65 at 36.) However, these cases involved much more egregious misstatements and much weaker curative disclosures. In *Rosenbaum Cap. LLC v. Bos. Commc'ns Grp., Inc.*, the company's statement that it had a "meritorious defense" in an

[20] (*See also* Am. Compl. ¶ 143 ("Due to the complex nature of patent litigation, we refer investors to the court's order and other court documents for further detail, which can be located through the FAQ section of our Investor Relations website. We also refer investors to the Risk Factors section in today's Form 10-Q for detail. We intend to continue to vigorously defend our patents but don't intend to go into more detail on that today.").) Other contemporaneous statements referred investors to the public record of the Nevada Litigation. (*See e.g.*, *id.* ¶ 141 ("The public record for the ANDA litigation is available for all to view and many have.").)

[21] These disclosures are evident both from the public statements and SEC filings directly referenced in the Amended Complaint as well as in the filings publicly available from the SEC; from filings throughout the USPTO patent prosecution process up through the end of the Class Period. (*See generally* Exs. 3–62.)

infringement action were insufficient where it took steps to design a new system with "unnecessary components in order to make the new system appear different from" the patent-holder's and obtained opinion letters from law firms that the company knew were based on insufficient knowledge. 445 F. Supp. 2d 170, 172, 176 (D. Mass. 2006). Likewise in *Meyer v. Jinkosolar Holdings Co.*, the Second Circuit found a generic warning of regulatory risk inadequate, where the company's public statements that it employed "pollution abatement equipment and . . . monitoring environmental teams on duty 24 hours a day" conflicted with concurrent private reports to environmental regulators of substantial, existing problems. 761 F.3d 245, 251 (2d Cir. 2014). While Defendants did not disclose the specific risk of Judge Du citing the Kurabayashi Study as the reason for overturning Amarin's patents, the Amended Complaint lacks any allegation that Defendants should have known of this possibility. *See Williams v. Globus Med, Inc.*, 869 F.3d 235, 243 (3d Cir. 2017) (company does not have a duty to disclose a risk that had not "actually materialized" at the time of the allegedly misleading prior disclosure).

Defendants' warnings also bring their statements under the PSLRA's safe harbor. Under the PSLRA, "forward-looking" statements are not actionable if they are "(1) identified as such, and accompanied by meaningful cautionary statements; or (2) immaterial; or (3) made without actual knowledge that the statement was false or misleading." *In re Aetna, Inc.*, 617 F.3d at 278 (citing 15 U.S.C. § 78u-5(c)). The PSLRA's definition of "forward-looking statement" includes "projections of future performance, plans and objectives for future operations, and assumptions underlying statements about future financial, economic or operational performance." *Id.* at 279 (citing 15 U.S.C. § 78u–5(i)(1)). This safe harbor for forward-looking statements overlaps with the Third Circuit's "bespeaks caution" doctrine, under which "cautionary language, if sufficient, renders the alleged [forward-looking] omissions or misrepresentations immaterial as a matter of

law." *EP Medsystems*, 235 F.3d 874 (quoting *In re Donald J. Trump Casino Sec. Litig.-Taj Mahal Litig.*, 7 F.3d 357, 371 (3d Cir. 1993)). "Under both the PSLRA and the bespeaks caution doctrine, cautionary language must be extensive, specific, and directly related to the alleged misrepresentation . . . ." *Lewakowski v. Aquestive Therapeutics, Inc.*, No. 21-3751, 2023 WL 2496504, at *5 (D.N.J. Mar. 14, 2023) (citing *In re Aetna*, 617 F.3d at 282; *In re Donald J. Trump*, 7 F.3d 357 at 371–72).

Each of the criteria for the PSLRA safe harbor are met here. Forward-looking statements are "broadly defined" in the PSLRA, *Avaya*, 564 F.3d at 255, to include, among other statements, those about "future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission" as well as "any statement of the assumptions underlying or relating to" such statements. 15 U.S.C. § 78u-5(i)(1)(C)–(D). As summarized above, each of the alleged statements about the Nevada Litigation address Amarin's intent to defend its patents, Amarin's belief and/or hope for how the litigation will proceed, Amarin's belief of whether it will succeed in the litigation and on appeal. (*See* Am. Compl. ¶¶ 138–53.) These sort of statements fit comfortably within the forward-looking statement definition. *See also Laasko*, 2022 WL 3444038, *5 ("litigation risk disclosures were forward-looking statements"). These statements were accompanied, often contemporaneously but also in Amarin's SEC filings from around the same time, with meaningful, specific warnings disclosing specific risks, such as that Thero "can't make any predictions [about the Nevada Litigation] other than stating that we intend to defend our patents vigorously." (Am. Compl. ¶ 142; *see also* Exs. 3–62.) Further, Defendants' forward-looking statements are nonactionable because Plaintiffs "have not sufficiently pleaded a strong inference that defendants acted with actual knowledge that their

projections were false or misleading." *Avaya*, 564 F.3d at 259. As the Amended Complaint fails to allege that Defendants lacked a reasonable basis for their opinions, they have also failed to plead actual knowledge. *See Intel Corp. Inv. Pol'y Comm. v. Sulyma*, 589 U.S. 178, 184 (2020) ("[T]o have 'actual knowledge' of a piece of information, one must in fact be aware of it.").

ii. Vascepa's "Unique" Characteristics

The Amended Complaint cites to a number of public statements made by Defendants—all by Thero except for one by Craig Granowitz ("Granowitz"), Amarin's Chief Medical Officer—about Vascepa's "unique" properties that differentiated it from existing available products. (Am. Compl. ¶¶ 99–110.) Plaintiffs allege that these were false or misleading statements that omitted key information because "Vascepa was not unique, and Amarin did not invent purified EPA or discover any of its medical characteristics." (*Id.* ¶ 111.) Therefore, Plaintiff concludes again, Amarin was not entitled to patent protection for Vascepa and only received a patent because it "withheld material information" from the USPTO examiner. (*Id.*)

Defendants argue that Plaintiffs' challenge to these statements "rests on the same flawed assertion of a purported failure to disclose the 'fragility' and 'vulnerability' of the MARINE patents." (ECF No. 58-1 at 43 (quoting Am. Compl. ¶¶ 13, 111).) Defendants further argue that the Amended Complaint's allegations regarding Vascepa's uniqueness "erroneously conflates *both* (i) obviousness with uniqueness and (ii) REDUCE-IT with MARINE." (*Id.* at 43.) Defendants conclude that several of the statements alleged in this section are inactionable puffery or forward-looking statements that fall under the PSLRA's safe harbor. (*Id.* at 44.)

Plaintiffs respond that statements making "specific comparisons" between two drugs are "actionable when scientific studies suggest" they are not. (ECF No. 65 at 39.) By calling Vascepa "unique," Defendants inaccurately asserted that Vascepa was different from Epadel, which the

Kurabayashi Study showed was not true. (*Id.*) Plaintiffs also point to two other studies—the JELIS study and Katayama study—that they allege demonstrated that Epadel, and therefore Vascepa, had these same qualities. (*Id.* at 39–40.) Plaintiffs argue that whether a drug is "unique" is a fact, not an opinion, and that even if it were an opinion, Defendants lacked a reasonable basis to express it. (*Id.* at 40.) Plaintiffs also argue that the several statements Defendants point to are neither puffery nor protected by the FSLA safe harbor. (*Id.* at 41–42.)

The Court finds that Plaintiffs have failed to allege any actionable statement within this group of twelve statements either. At the outset, a number of the statements constitute inactionable puffery as "vague and general statements of optimism 'constitute no more than "puffery" and are understood by reasonable investors as such.'" *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 538 (3d Cir. 1999) (quoting *In re Burlington Coat*, 114 F.3d at 1428 n.14). "Such statements, even if arguably misleading, do not give rise to a federal securities claim because they are not material." *Id.* (citations omitted). Statements that a drug product is "unique," "far superior" to other generic drugs, should do "very well" and will be "well received" are puffery because they are "not the kind of statements that a reasonable investor would have relied upon." *Bauer v. Eagle Pharms., Inc.*, No. 16-3091, 2017 WL 2213147, at *12 (D.N.J. May 19, 2017) (citing *In re Burlington Coat*, 114 F.3d at 1426); *see also In re Neurotrope, Inc. Sec. Litig.*, 315 F. Supp. 3d 721, 734 (S.D.N.Y. 2018) (finding puffery when stating that a drug trial results "provide exciting evidence of a new therapeutic approach"). Likewise here, the Amended Complaint's allegations that Vascepa is "the single most significant advance" in preventative cardiovascular care or that the REDUCE-IT results show a "new paradigm in treatment" are inactionable puffery. (Am. Compl. ¶¶ 100–01.)[22]

[22] (Am. Compl. ¶ 100 ("An additional 25% relative risk reduction in REDUCE-IT, on top of well-controlled LDL cholesterol through statin therapy, positions Vascepa as the single most significant advance in preventative cardiovascular drug therapy since the advent of statin therapy."); *id.* ¶ 101 ("This is a – with the REDUCE-IT results an opportunity to provide medical therapy that is a new paradigm in treatment

Plaintiffs say the uniqueness claims were misleading because Amarin was "not entitled to patent protection for Vascepa" because the only reason it received patents in the first place was because it "withheld material information" from the USPTO examiner. (Am. Compl. ¶ 111(b).) This claim again turns on the argument that Defendants knew or should have known that the Kurabayashi Study would eventually be cited by Judge Du as part of her decision invalidating Vascepa's patents. As explained above, Plaintiffs have not alleged facts with particularity either that Defendants did "not honestly believe[]" or lacked a "reasonable basis" to believe the patents would be upheld. *City of Edinburgh*, 754 F.3d at 170. Therefore, statements that Vascepa was unique (and impliedly different from Epadel) are opinions which Defendants had a reasonable belief to express.

To the extent Plaintiffs allege that these statements were inaccurate not just because of Kurabayashi but also because of the JELIS and Katayama studies, (ECF No. 65 at 39–40 (discussing same)), these allegations are likewise inadequate. While Plaintiffs claim that Amarin "buried" the Kurabayashi Study from the USPTO—which, as the Court has already explained, is unsupported by any particular allegations—Plaintiffs cannot even make the same claim about either JELIS or Katayama. As alleged in the Amended Complaint, the patent examiner's rejection of Amarin's application for the MARINE patent was rejected several times in part based on the Katayama study. (Am. Compl. ¶¶ 56, 61.) While the Amended Complaint alleges that Defendants "knew the JELIS study in Japan had already proven that 'EPA treatment reduced the frequency of major coronary events'" at the time Amarin launched the REDUCE-IT Trial, its executives publicly "acknowledged it closely mirrored the JELIS study," with Granowitz telling investors

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. . ."); *id.* ¶ 107 ("I'm hearing tremendous support for Vascepa from the medical community that is familiar with this important drug. They emphasize, as do the medical society, that the results of REDUCE-IT should not be generalized to any other product."); *id.* ¶ 109 ("Vascepa represents a new class of proven preventative therapy.").)

several months before the start of the Class Period (when the REDUCE-IT results were announced) that "we believe that REDUCE-IT has a very high probability of success" because "JELIS was the most similar to REDUCE-IT in terms of the drug, a pure EPA product as well as the dosing." (*Id.* ¶ 79.)[23] Because the Katayama and JELIS studies were public knowledge and admittedly disclosed by Defendants, differentiating Vascepa from other drugs is not misleading. *See In re Celgene Corp. Sec. Litig.*, No. 18-4772, 2019 WL 6909463, at *12 (D.N.J. Dec. 19, 2019) (finding no actionable statements where the "shortcomings for clinical studies" that plaintiffs allege defendant failed to disclose "was publicly disclosed and acknowledged by" defendant); *see also In re Sanofi-Aventis Sec. Litig.*, No. 07-10279, 2009 WL 3094957, at *5 (S.D.N.Y. Sept. 25, 2009) (finding no actionable statements where allegedly non-disclosed "safety data" was "unequivocally demonstrate[d]" by the complaint to have been "made available to the public through [defendant's] press releases, S.E.C. filing, and various medical publications").

Indeed, the Court notes the critical distinction between the MARINE Trial and the REDUCE-IT Trial. The MARINE Trial demonstrated that Vascepa reduced triglycerides in patients with severe hypertriglyceridemia. (Am. Compl. ¶ 51.) Throughout its application to the

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[23] Further undermining the Amended Complaint's allegation that the statements about REDUCE-IT were misleading in light of JELIS, Defendants further cite the Court to other portions of their SEC filings in which they repeatedly disclosed that the REDUCE-IT Trial sought to expand on the JELIS study. (*See* Ex. 52 at 12 ("In Japan, ethyl-EPA is marketed under the product name of Epadel . . . . Due to the limitation of JELIS, further study was needed through the REDUCE-IT study to determine the clinical benefit, if any, of EPA therapy in statin-treated patients with elevated triglyceride levels in a patient population beyond that studied in JELIS."); *see also id.* ¶ 54 at 10 (same).)

Further, the Court notes that in one of the prior securities fraud class action suits against Amarin, the plaintiffs there alleged that the defendants—Amarin and several executives, including Thero—made actionable misstatements in 2010 to 2013 when they "repeatedly miscited JELIS as support for the efficacy of Vascepa, despite their actual knowledge of critical distinctions between JELIS and ANCHOR and REDUCE–IT." *In re Amarin Corp. PLC.*, No. 13-6663, 2015 WL 3954190, at *8 (D.N.J. June 29, 2015). In other words, while those plaintiffs alleged actionable statements because the defendants compared REDUCE-IT and JELIS, here Plaintiffs allege actionable statements because Defendants did not talk about JELIS when discussing REDUCE-IT. While the opposite allegations are certainly not preclusive, the inconsistency is striking.

USPTO, Amarin maintained that the MARINE Trial showed "a reduction in triglycerides and ApoB without raising LDL-C levels." (*Id.* ¶ 53). It was on the basis of the MARINE Trial results that Amarin sought and eventually received patent protection for Vascepa. (*Id.* ¶¶ 53–72.) The Amended Complaint's allegations relating to the patent prosecution before the USPTO make no mention of Vascepa's use for reducing cardiovascular risk (*i.e.* the REDUCE-IT indication). (*Id.*) In contrast, the REDUCE-IT Trial demonstrated that "patients taking purified EPA were at substantially less risk for a cardiovascular event than patients taking a placebo." (*Id.* ¶ 80.) As Judge Du explained in finding the REDUCE-IT results irrelevant to Amarin's secondary considerations arguments, "there is no nexus between REDUCE-IT and the Asserted Claims" for the patents issued by the USPTO. *Hikma Pharms. USA Inc.*, 449 F. Supp. 3d at 1010. While the patents for Vascepa were issued based on the MARINE method, any claim as to uniqueness related to the REDUCE-IT indication. (*See, e.g.*, Am. Compl. ¶ 100 (describing an "additional 25% relative risk reduction in REDUCE-IT" as "the single most significant advance in preventative cardiovascular drug therapy").)[24] Even reading these statements to mean that Defendants were representing that Amarin's REDUCE-IT indication was unique, those statements were not

[24] (*See* Am. Compl. ¶ 100 ("An additional 25% relative risk reduction in REDUCE-IT, on top of well-controlled LDL cholesterol through statin therapy, positions Vascepa as the single most significant advance in preventative cardiovascular drug therapy since the advent of statin therapy."); *id.* ¶ 101 ("We continue to reinforce that REDUCE-IT results are unique to Vascepa it cannot be generalized any prior generation add-on to statin, such as fenofibrates and that the REDUCE-IT results cannot be generalized to common fish oil or omega-3 mixture products, particularly those that contain the omega-3 acid, DHA. . . . This is a – with the REDUCE-IT results an opportunity to provide medical therapy that is a new paradigm in treatment . . . ."); *id.* ¶ 102 ("Vascepa has demonstrated clinical effects that have not been shown for any other product. The clinical effects of Vascepa demonstrated in REDUCE-IT cannot be generalized to any other product."); *id.* ¶ 104 ("We do not envision that we will compete with therapies for managing LDL cholesterol. Rather, Vascepa presents a new opportunity for healthcare professionals to help patients reduce their cardiovascular risk."); *id.* ¶ 107 ("I'm hearing tremendous support for Vascepa from the medical community that is familiar with this important drug. They emphasize, as do the medical society, that the results of REDUCE-IT should not be generalized to any other product."); *id.* ¶ 109 ("Vascepa represents a new class of proven preventative therapy. Vascepa is the first and only drug with this new cardiovascular risk reduction indication. Our launch of Vascepa for this new indication reflects the uniqueness of Vascepa.").)

rendered inactionable by Judge Du's decision, which did not touch on Vascepa's qualities or characteristics for the REDUCE-IT indication, and therefore did not render these statements false.

Other statements are not adequately alleged to be misleading because on their face they do not refer to Vascepa. The Amended Complaint alleges falsity in that "Vascepa was not unique." (Am. Comp. ¶ 111(a).) However, some of the complained-of statements refer not to Vascepa—Amarin's drug—but to EPA, the compound Vascepa contains, such as Thero's November 2018 statement that "[p]ublications in recent years have shown that the clinical effects *of the active ingredient* in Vascepa are unique." (*Id.* ¶ 101 (emphasis added).)[25] As to the Amended Complaint's claim that "Amarin did not invent purified EPA or discover any of its medical characteristics," (*id.* ¶ 111(a)), Plaintiffs cite to no statements by Amarin or its employees suggesting that they did. The Court must read the alleged misstatements in the context in which they were made. *City of Edinburgh*, 754 F.3d at 171. Read in context, these statements fail to identify anything "materially misleading" about these statements. *In re NAHC*, 306 F.3d at 1330 (citing *In re Burlington Coat*, 114 F.3d at 1419).

iii. Financial Prospects of REDUCE-IT and Vascepa's Prospects

In the final group of statements Plaintiffs cite in support of their claim, Defendants make statements regarding Amarin's financial prospects resulting from the results of the REDUCE-IT Trial. (Am. Compl. ¶¶ 112–36.) Of the 25 quoted statements, only three were made or signed by

[25] (*See also* Am. Compl. ¶ 102 ("The active pharmaceutical ingredient in Vascepa has a unique molecular structure. Vascepa has demonstrated clinical effects that have not been shown for any other product. The clinical effects of Vascepa demonstrated in REDUCE-IT cannot be generalized to any other product."); *id.* ¶ 103 ("There's data out there showing that EPA, . . . *the active ingredient* in our drug, has a positive effect on each of those steps . . . ." (emphasis added)); *id.* ¶ 105 ("As a reminder, Vascepa capsules are not an omega-3 mixture but a drug product *consisting of icosapent ethyl*, the single active ingredient of which has been shown to have clinical effects which are different from any other drug." (emphasis added)); *id.* ¶ 106 ("Vascepa is – has a *mechanism of action*, which is unique. The FDA has deemed it to be a new chemical entity." (emphasis added)); *id.* ¶ 108 ("This is a unique molecule. It's been deemed a new chemical entity by the FDA. It is – it has multiple effects that have not been shown for any other molecule.").)

Kalb, with the rest made by Thero. (*Id.*) The Amended Complaint alleges that these statements were actionable because they failed to disclose (1) if it lost patent protection, Amarin would have to compete with generic manufacturers and would not have the same market share, (2) the loss of patent protection would "dramatically undermine the positive REDUCE-IT results," and (3) Amarin was "not entitled" to its patents and only received them because it "withheld material information . . . from the USPTO." (*Id.* ¶ 137.)

Defendants argue that the Amended Complaint does not allege an actionable omission because of Amarin's extensive disclosure "warn[ing] of these very risks regarding both MARINE patent invalidity and generic competition." (ECF No. 58-1 at 45.) Further, Defendants contend that the financial predictions are inactionable opinions because the Amended Complaint does not allege that Thero and Kalb did not honestly believe their opinions and also that they fall under the PSLRA's safe harbor. (*Id.* at 45–47.) Finally, Defendants argue that some statements in this section are puffery or accurate statements of historical fact. (*Id.* at 47–48.) Plaintiffs' response, as with the prior two groups of statements, turns on the argument that Defendants failed to "disclos[e] material information concerning the validity of Vascepa's patents." (ECF No. 65 at 20–21.) Applying this allegation, Plaintiffs reason that Defendants' disclosures of litigation risks were inadequate, that their opinions about Vascepa's financial prospects lacked a reasonable basis, and that the safe harbor is unavailable. (*Id.* at 22–30.)

The Court finds that as a matter of law, Defendants' statements about the financial prospects from the REDUCE-IT study are not materially false or misleading, largely for the reasons explained in the preceding sections. The challenged statements here all express Defendants' belief in the scope of Vascepa's success in light of the REDUCE-IT Trial's results. (Am. Compl. ¶¶ 112–36.) In pleading why these statements are allegedly false, each of the three

reasons Plaintiffs give ties back to the claim that the Individual Defendants' failed to disclose that it could lose patent protection, which in turn is based on the previously-addressed, unsubstantiated claim that the undisclosed Kurabayashi Study was fatal to Amarin's patent claim. (*Id.* ¶ 137.) Plaintiffs' opposition brief affirms that this is the basis for Plaintiffs' claims about these statements. (ECF No. 65 at 22–30.) Although no further discussion is necessary to find these statements inactionable, the Court briefly addresses additional arguments when only tend to bolster and support this outcome.

First, the statements are all inactionable opinions. As one representative statement alleged, at a September 2018 call announcing the results of the REDUCE-IT Study, Thero said:

> Fast forward through over a decade and hundreds of millions of dollars of big pharma clinical development to REDUCE-IT. With approximately 25% relative risk reduction on top of statin therapy now demonstrated, we have confirmed that our easy-to-use drug, that's inexpensive, with broad reimbursement coverage, significantly reduces cardiovascular risk. It thus has the potential to overcome the limitations of multiple blockbuster prior-generation therapies. It thus has the potential to be a significant blockbuster and help millions of patients reduce cardiovascular risk on top of standard-of-care statin therapy.

(Am. Compl. ¶ 113.) The statements from Thero or Kalb reflect similar projections about the "potential for Vascepa to help millions of patients," (*id.* ¶ 114), or their belief "that REDUCE-IT results will help transform Vascepa into becoming a multibillion-dollar brand," (*id.* ¶ 115).[26] Each

[26] (*See also* Am. Compl. ¶ 115 ("[T]he REDUCE-IT results positions Vascepa to lead a new paradigm in patient care beyond cholesterol management. . . . While we do believe that REDUCE-IT results will help transform Vascepa into becoming a multibillion-dollar brand, we intend to wait until healthcare professionals better appreciate the results for the REDUCE-IT study and better appreciate the existing managed care coverage in affordable pricing of Vascepa before we provide revenue guidance."); *id.* ¶ 116 ("[R]oughly 1 in 4 adults in the United States have elevated triglycerides, but fewer than 4% of those patients are treated with any therapy . . . . Or is it all 25%, and we're about twice but that's about $80 billion. I don't think we'll get there, but that's the size of the potential opportunity."); *id.* ¶ 117 ("We will be pursuing a[n] expanded indication with the FDA for cardiovascular risk prevention, and we believe this is a multibillion-dollar opportunity."); *id.* ¶ 121 ("We anticipate Vascepa revenue growth to accelerate further after label expansion approval and with a larger sales team, and then again after we commence promotion

of these expressions of Vascepa's potential is "a belief, a view, or a sentiment which the mind forms of persons or things." *Omnicare*, 474 U.S. at 183 (citation omitted) (cleaned up).

Thus, whether Plaintiffs have alleged securities fraud turns on whether they have adequately alleged that an opinion "(i) was not sincerely believed when made; (ii) contains an expressly embedded, untrue factual assertion; or (iii) reasonably implies untrue facts and omits appropriate qualifying language." *City of Warren Police*, 70 F.4th at 686. Plaintiffs argue that "Defendants may not describe a favorable picture of material issue without including the details that would have presented a complete and less favorable one." (ECF No. 65 at 21 (quoting *Industriens Pensionsforsikring v. Becton, Dickinson & Co.*, 620 F. Supp. 3d 167, 186 (D.N.J. 2022)).)[27] Plaintiffs have failed to allege any facts supporting the assertion that "Defendants understood that Vascepa's patents could not withstand the scrutiny of litigation." (ECF No. 65 at 17.) As explained above, the mere existence of the Kurabayashi Study—Plaintiffs' only basis for

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of Vascepa for cardiovascular risk reduction on television and through other media."); *id.* ¶ 122 ("With the success of our launch of Vascepa for this important new indication, we believe that Amarin will create growth and significant shareholder value."); *id.* ¶ 123 ("[W]e're working to be at a support multiple billions in revenues, and we're using a strategy that has multiple suppliers competing against themselves."); *id.* ¶ 124 ("But if we just look at the population of patients with triglycerides from 135 and above, that's about 90 million people in United States. If we look at statin treated patients with elevated triglycerides 135 and above, that's about 15 million patients in the United States."); *id.* ¶ 126 ("At this time, we are projecting that total net revenue for 2020 will be in the range of $650 million to $700 million, mostly from sales of Vascepa in the United States. . . . However . . . at this time, we are not providing guidance regarding annual revenue levels beyond 2020."); *id.* ¶ 127 ("We are committed to making Vascepa a multibillion-dollar brand and a standard of care for patients with persistent high cardiovascular risk."); *id.* ¶ 130 ("This is the advent of a new era in preventative cardiovascular care."); *id.* ¶ 131 ("As previously described, we believe that a U.S. sales force of 800 sales representatives, supported by our other promotional activities, is positioned to make Vascepa a multibillion-dollar brand."); *id.* ¶ 134 ("VASCEPA is rapidly becoming a new pillar in preventative cardiovascular care. We have the drug, the signs, the people and the resources to, and we believe, being quite successful in the U.S., Europe and rest of the world.").

[27] In *Industriens Pensionsforsikring*, Judge Chesler found that complaint had adequately alleged an actionable omission because defendants had made rosy financial projections about their drug without disclosing that the FDA had told the company that there were "concerning" issues with the product and that the company should not ship the product with the issues." 620 F. Supp. 3d 167 at 186. The complaint contained "allegations from multiple confidential witnesses demonstrating that critical employees working on [the drug] and its defects . . . understood that the FDA in this meeting de facto demanded the imposition of a ship hold until the BD could resolve the defects." *Id.*

their allegation that Defendants should have known of that their patents were invalid—is insufficient to plead that Defendants' had such knowledge and is not a risk Defendants were required to disclose to the investing public. While the projections for Amarin's market power after REDUCE-IT were predicated on Amarin's ability to maintain its patents, this risk was disclosed, both concurrently with the cited statements in the Amended Complaint, and in Amarin's SEC filings. Thus, the Court finds that the Amended Complaint fails to allege with particularity that Defendants lacked a reasonable basis for their opinions, that they were not sincerely held, or that they contained untrue factual assertions.

* * *

In sum, the Amended Complaint has not adequately alleged that any of Defendants' statement about the USPTO proceedings, the Nevada Litigation, Vascepa's characteristics, or Amarin's financial prospects based on the REDUCE-IT Study were actionable, because they were reasonably held opinions accompanied by appropriate disclosures, supported by reasonable belief, appropriately caveated, and protected by the PSLRA's safe harbor.[28] At the Amended Complaint's core is Plaintiffs' allegation that Amarin and its executives knew that the company was not entitled to patent protection for Vascepa but nonetheless sought and defended the patents. Plaintiffs' theory of liability would impose a duty that Congress sought to avoid through the PSLRA's heightened pleading standard. *See In re NAHC*, 306 F.3d at 1330 ("[L]iability cannot be imposed on the basis of subsequent events."). The Honorable Michael Vazquez, U.S.D.J. (ret.) explained the concern well:

[28] As explained at the outset, given Plaintiffs' pleading approach to quote large volumes of text without specifying how each statement was allegedly misleading, the Court does not quote and discuss every single statement from the Amended Complaint. For the avoidance of doubt, the Court notes that it has assessed each statement in Plaintiffs' Amended Complaint, even if not discussed herein. For the above-mentioned reasons, the Court finds that Plaintiffs fail to allege an actionable omission or misstatement.

> Plaintiffs seem to contend that a company must also make a complete mea culpa when disclosing the investigation and its potential legal implications. Such a position does not find support in the law. . . . Plaintiffs do not claim that Defendants made a misrepresentation or actionable omission concerning the nature of the investigation itself nor as to the potential legal liability faced by [the corporate defendant]. Plaintiffs do contend, however, that [the corporate defendant's] disclosures were misleading because they concealed the true extent of the company's legal exposure . . . The law required [the corporate defendant] to disclose the investigation and its potential legal ramifications, which [the corporate defendant] appears to have done.

In re Galena Biopharma, Inc. Sec. Litig., No. 17-929, 2019 WL 5957859, at *10–11 (D.N.J. Nov. 12, 2019). Defendants cannot pluck a piece of evidence that the Court in the Nevada Litigation relied on in reaching its decision to argue now that Defendants' decade of optimistic opinions about their patents were fraudulent, absent any particularized allegations that Defendants had conflicting information at the time or otherwise lacked a reasonable basis for their opinions. The Amended Complaint does not do so here, and this claim must fail.

2. Inference of Scienter

To survive dismissal, Plaintiffs must also adequately plead scienter, which is "the defendant's intention to deceive, manipulate, or defraud," *Tellabs*, 551 U.S. at 313 (citation and quotations omitted), requiring "a knowing or reckless state of mind," *Avaya*, 564 F.3d at 267 (citing *Advanta.*, 180 F.3d at 534–35). "Under the PSLRA's second pleading requirement, a plaintiff must 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Id.* at 267 (quoting 15 U.S.C. § 78u–4(b)(2)). This standard is met "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. The Court conducts this analysis "holistically to determine whether [the complaint's] allegations, 'taken collectively, give rise to a strong inference of scienter, not whether any

individual allegation, scrutinized in isolation, meets that standard.'" *In re Hertz Glob. Holdings Inc*, 905 F.3d 106, 114 (3d Cir. 2018) (quoting *Tellabs, Inc.*, 551 U.S. at 323). "[O]missions and ambiguities count against inferring scienter." *Tellabs, Inc.*, 551 U.S. at 323.

The Amended Complaint asserts that its alleged facts permit the "strong[] infer[ence] [that] Defendants knew or recklessly disregarded that their Class Period statements were materially false or misleading to investors." (Am. Compl. ¶ 155.) Plaintiffs further allege several facts they contend support scienter. First, Plaintiffs allege that because Vascepa was Amarin's sole product on which Amarin's financial success depended, the Individual Defendants "exclusively focused on issues concerning Vascepa in their day-to-day work." (*Id.* ¶ 157; *see also id.* ¶¶ 156–61.) Second, Plaintiffs point to the Individual Defendants' repeated, detailed public statements about Vascepa as showing they played an "integral role" in REDUCE-IT and the MARINE litigation. (*Id.* ¶ 163; *see also id.* ¶¶ 162–69.) Third, Plaintiffs contend that the Individual Defendants' stock trading history during the Class Period, in which they "sold over 5.4 million shares of Amarin ADSs at artificially inflated prices," supports scienter. (*Id.* ¶ 170; *see also id.* ¶¶ 170–77.) Finally, the Amended Complaint alleges that Thero's and Kennedy's departures from the company in April 2021 support an inference of wrongdoing. (*Id.* ¶¶ 178–79.)

Defendants respond that the Amended Complaint's discussion of the Individual Defendants' stock sales, which may be probative of motive, does not establish scienter because the scope and timing of the sales were not suspicious. (ECF No. 58-1 at 48–55.) Defendants argue that Plaintiffs have offered no fact—"from a confidential witness, internal document, or otherwise"—supporting the claim that the Individual Defendants "knew or believed the MARINE patents shouldn't be granted, were invalid when granted, or would be invalidated in the MARINE Patent Litigation." (*Id.* at 56.) Defendants contend that the more compelling inference from Defendants'

conduct is that they believed in their patents and that Vascepa would have the financial success they expected. (*Id.* at 56–57.) Defendants argue that the remaining allegations in the Amended Complaint—the importance of Vascepa to Amarin, the Individual Defendants' seniority at the company, and Thero's and Kennedy's retirement—even taken together are not sufficient to support a strong inference of scienter. (*Id.* at 57–59.)

Here, the Amended Complaint's scienter allegations are insufficient to satisfy the PSLRA's "strong inference" requirement. The Court begins with Plaintiffs' allegations of "reckless or conscious behavior." *Avaya*, 564 F.3d at 267. "Conscious misbehavior involves 'intentional fraud or other deliberate illegal behavior.'" *In re Radian Sec. Litig.*, 612 F. Supp. 2d 594, 613 (E.D. Pa. 2009) (quoting *Advanta*, 180 F.3d at 535). "A reckless statement is one involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Avaya*, 564 F.3d at 267 n.42 (quoting *Advanta*, 180 F.3d at 535).

Plaintiffs make three related arguments about the importance of Vascepa to Amarin and the Individual Defendants' involvement with the Nevada Litigation. The basic allegations Plaintiffs rely on for these arguments are sufficiently alleged. Vascepa was Amarin's "sole product," to which the company "devoted substantial resources." (Am. Compl. ¶ 156.) The Individual Defendants each held senior leadership positions at the company during the Class Period, and Thero and Kennedy were executives at the company during the patent prosecution. (*Id.* ¶¶ 23–25, 163.) Plaintiffs allege that the Individual Defendants were "highly sophisticated" as a result of their managerial (Thero), legal (Kennedy), and financial (Kalb) experience. (*Id.* ¶¶ 157–60.) All three Individual Defendants spoke to investors about the Nevada Litigation, Vascepa's

financial significance to Amarin, and the REDUCE-IT Results. (*Id.* ¶¶ 164–68; *see also id.* ¶¶ 99–153.) As such, Plaintiffs have pled facts sufficient to infer that given Vascepa's importance to the company, the Individual Defendants would have been focused on the Nevada Litigation and familiar or even involved with major litigation decisions.

However, Plaintiffs carry their inferences too far by concluding that therefore the alleged misrepresentations and omissions—*i.e.* their patents' fundamental flaw from failing to disclose the Kurabayashi Study—were "of such a nature [that] they would have been approved by corporate officials sufficiently knowledgeable about the Company to know those statements and omissions were false and misleading." (*Id.* ¶ 161.) Plaintiffs' allegations that the Individual Defendants were focused on Vascepa and winning the Nevada Litigation does not carry the inference that they therefore knew or recklessly disregarded the patents' vulnerabilities. Plaintiffs cite *Avaya* for the proposition that "the most powerful evidence of scienter is the content and context of [defendants'] statements themselves." 564 F.3d at 269. True, however in *Avaya*, this referred to chief financial officer's "explicit[]" denials that the company was discounting its products in the face of pricing pressure in response to "repeated questions about pricing by analysts." *Id.* In other words, the fact that a company officer makes a statement about a topic does not necessarily support the inference that he knows all facts relevant to that topic. *Id.* at 270 ("The mere fact that a defendant made a statement about earnings, therefore, does not necessarily imply he would have been aware of particular pricing developments."). *Avaya* may be factually similar had analysts asked about the Kurabayashi Study and the possibility of Amarin losing the Nevada Litigation because of it, and in response Individual Defendants denied that possibility. *See Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 246 (3d Cir. 2013) (distinguishing *Avaya* because "in *Avaya* the individuals who denied

that there was intense competition were responding to pointed inquiries from analysts during multiple conference calls that addressed pricing problems").

Plaintiffs do not allege anything comparable here. Instead, Plaintiffs call out only general statements by the Individual Defendants that indicate their focus on the patent litigation. (Am. Compl. ¶¶ 162–69.) The Amended Complaint alleges that Kennedy said he "[l]ed Amarin's strategy" in the successful prosecution of over 40 patents, (*id.* ¶ 163), which may refer to the six MARINE patents challenged in the Nevada Litigation. Regarding Thero, the Amended Complaint cites Thero's statement that he had been "part of Amarin" since the "genesis" of Vascepa. (*Id.* ¶ 164.) After the Nevada Litigation commenced, Thero and Kalb both made statements that Amarin was "focused on" or "prioritizing" wining the litigation. (*Id.* ¶¶ 166–68.) In contrast to these broad statements of Defendants' priorities, the decision on the importance of the Kurabayashi Study, whether to submit it to the USPTO, and whether to separately raise it in communications with the examiner are specific considerations and granular details within the broader context of the patent litigation. Plaintiffs offer no particularized allegations that the Individual Defendants were ever asked about the Kurabayashi Study or were involved in any decisions about how to use it in the patent prosecution. Therefore, these statements by the Individual Defendants do not create a strong inference that Plaintiffs knew about the alleged concealment of the Kurabayashi Study from the examiner.[29]

[29] The other cases Plaintiffs cite on this point, (ECF No. 65 at 44–45), likewise support the general proposition that an executive who publicly professes expertise on a subject can broadly be inferred to know what is happening within that subject at the company. *See Allegheny Cnty. Employees' Ret. Sys. v. Energy Transfer LP*, 532 F. Supp. 3d 189, 203 (E.D. Pa. 2021); *In re PTC Therapeutics, Inc. Sec. Litig.*, No. 16-1124, 2017 WL 3705801, at *17 (D.N.J. Aug. 28, 2017); *Gauquie v. Albany Molecular Rsch., Inc.*, No. 14-6637, 2016 WL 4007591, at *2 (E.D.N.Y. July 26, 2016). They do not support the inference that because the Individual Defendants were focused on Vascepa and the Nevada Litigation, they were aware of the Kurabayashi Study, considered its potential relevance to Amarin receiving or defending its patents, and therefore possessed requisite scienter when speaking about the Nevada Litigation.

Plaintiffs' related reliance on the "core operations" doctrine fails for the same reason. (ECF No. 65 at 45–46.) "[U]nder the core operations doctrine, misstatements and omissions made on 'core matters of central importance' to the company and its high-level executives gives rise to an inference of scienter when taken together with additional allegations connecting the executives' positions to their knowledge." *In re Urban Outfitters, Inc. Sec. Litig.*, 103 F. Supp. 3d 635, 653–54 (E.D. Pa. 2015) (quoting *Rahman*, 736 F.3d at 246). This doctrine is insufficient by itself to establish scienter but should be taken "in consideration when viewing the entirety" of the Amended Complaint's allegations. *In re: Enzymotec Sec. Litig.*, No. 14-5556, 2015 WL 8784065, at *18 (D.N.J. Dec. 15, 2015). As explained above, Plaintiffs have certainly alleged adequately that Vascepa was important to Amarin and the Individual Defendants. The USPTO prosecution and Nevada Litigation did not involve an ancillary part of Amarin's business; plainly, the Individual Defendants were sensitive to Amarin's patents. However, the core operations doctrine does not permit imputing the requisite scienter regarding any statement made within a broad perimeter of the relevant core operations to an executive. *See Rahman*, 736 F.3d at 246 (distinguishing the core operations doctrine's application in *Avaya*); *see also Nat'l Junior Baseball League v. Pharmanet Dev. Grp. Inc.*, 720 F. Supp. 2d 517, 556 (D.N.J. 2010) ("[I]t is not automatically assumed that a corporate officer is familiar with certain facts just because these facts are important to the company's business; there must be other, individualized allegations that further suggest that the officer had knowledge of the fact in question."); *Advanta*, 180 F.3d at 539 (rejecting "allegations that a securities-fraud defendant, because of his position within the company, 'must have known' a statement was false or misleading"). While the core operations doctrine offers weak support for inferring scienter, it is not enough here.

In contrast, here, Plaintiffs' allegations regarding Thero's and Kennedy's departures from the company do not support an inference of scienter. Plaintiffs point to the fact that they left in April 2021—"seven months after the Federal Circuit affirmed the District Court's invalidation of Vascepa's patents"—as evidence of their state of mind. (ECF No. 65 at 46.) The Third Circuit has found that "[r]esignations or terminations might form a piece to the scienter puzzle . . . if, for example, a relatively contemporaneous and public firing is accompanied by extreme corporate punishment such as the denial of previously accrued benefits." *Fain v. USA Techs., Inc.*, 707 F. App'x 91, 97 (3d Cir. 2017) (citing *Abrams v. Baker Hughes Inc.*, 292 F.3d 424, 434 (5th Cir. 2002)).

The Amended Complaint does not allege that the departures were either contemporaneous with the announcement of bad news or accompanied by any punishment. Thero and Kennedy both left the company in April 2021, (Am. Compl. ¶¶178–79), which was seven months after the Federal Circuit affirmed Judge Du's decision. However, Amarin's loss in the Nevada Litigation did not "reveal" any wrongdoing; in other words, as explained above, no facts came to light through Judge Du's decision or the Federal Circuit's affirmance that Amarin, let alone any Individual Defendant, concealed the Kurabayashi Study or that at the time the USPTO issued the patents, Defendants knew or even suspected them to be invalid. Therefore, the fact that two Individual Defendants' departures from the company followed the court decisions, absent any allegation that they were in any way punished or censured, does not evidence scienter. *See Hoey v. Insmed Inc.*, No. 16-4323, 2018 WL 902266, at *23 (D.N.J. Feb. 15, 2018) ("Plaintiff fails to adequately allege an extraordinary corporate punishment against Dr. Gupta.").[30] Further, Judge

[30] In fact, rather than punishment, Thero and Kennedy received consulting contracts with Amarin after departing, as set out in Amarin's public Form 8-Ks filed in April 2021. (*See* Exs. 60, 61.)

Du's decision citing the Kurabayashi Study was handed down in March 2020, over one year before the executives' departures. This is not the "relatively contemporaneous and public firing," *Fain*, 707 F. App'x at 97, that could support scienter. *Cf. Van Dongen v. CNinsure Inc.*, 951 F. Supp. 2d 457, 474 (S.D.N.Y. 2013) (inference of scienter supported by retirement of executive "on the same day" a research firm released a negative report about the company); *Hoey*, 2018 WL 902266, at *23 (inference of scienter not found even where executive resigned "shortly after" negative results announced).[31]

Finally, the Court considers the Amended Complaint's allegations related to the Individual Defendants' stock sales. While "motive and opportunity" do not offer an "independent route to scienter" following *Tellabs*, particularized allegations regarding motive and opportunity may, in combination with other allegations, support a strong inference of scienter. *Avaya*, 564 F.3d at 277 (citing *Tellabs*, 551 U.S. at 323–29). Although the Court "will not infer fraudulent intent from the mere fact that some officers sold stock," *id.* at 279 (quoting *Advanta*, 180 F.3d at 540), "if the stock sales were *unusual in scope or timing*, they may support an inference of scienter," *id.* (emphasis added). "Whether a sale is 'unusual in scope' depends on factors such as 'the amount of profit made, the amount of stock traded, the portion of stockholdings sold, or the number of insiders involved,'" *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 277 (3d Cir. 2006) (quoting *Wilson v. Bernstock*, 195 F. Supp. 2d 619, 635 (D.N.J. 2002)), as well as "whether the

[31] Statements quoted in the Amended Complaint that Thero's replacement would be "responsible for reversing the business' decline" and that Thero must "take responsibility" for Amarin's loss in the Nevada Litigation, (Am. Comp. ¶ 178), are generic statements that would be expected about any executive of a company that experienced a significant litigation disappointment, as the Nevada Litigation certainly was. *See In re Hertz*, 905 F.3d at 119 ("But pleading scienter requires more than pleading a link between bad news and an executive's resignation. Changes in leadership are only to be expected when leadership fails. That is not, in itself, a symbol of fraud.").

sales were 'normal and routine,' and whether the profits were substantial relative to the seller's ordinary compensation," *id.* (quoting *In re Burlington Coat*, 114 F.3d at 1423).

Plaintiffs would infer scienter from the Amended Complaint's allegations that the Individual Defendants "sold over 5.4 million shares of Amarin ADSs at artificially inflated prices" during the Class Period. (Am. Compl. ¶ 170; *see generally id.* ¶¶ 170–77.) As summarized in its embedded charts, the Amended Complaint alleges that during the two-and-a-half year Class Period, Thero sold shares worth $36,790,688, Kennedy sold shares worth $36,504,087, and Kalb sold shares worth $9,779,380. (*Id.* ¶ 170.) Thero and Kalb had not sold any shares in the two years prior to the start of the class period, during which time Kennedy sold shares worth $2,138,688. (*Id.* ¶¶ 173–75.) On the day the Class Period began—which is also the day the REDUCE-IT results were announced—Kennedy sold 83.21% of his holdings, at the time worth over $11 million. (*Id.* ¶ 173.) On that same day, Kalb sold 90.91% of his then-holdings, which were worth over $1.5 million. (*Id.* ¶ 174.)[32] Plaintiffs argue that these sales are "suspicious" and support the inference that the Individual Defendants knew the patents would eventually be invalidated. (ECF No. 65 at 48–57.)

Defendants disagree. (ECF No. 58-1 at 48–55.) According to Defendants, Plaintiffs' focus on Kalb's and Kennedy's sales made on the day the Class Period began omits that Thero made 68 of the 73 statements which Plaintiffs challenge. (*Id.* at 49.) Defendants argue that Kalb's and

[32] The Court recognizes that the amounts and percentages of the Individual Defendants' stock sales alleged in the Amended Complaint do not perfectly add up. For example, while the Amended Complaint alleges that Kalb sold 90.91% of his Amarin ADS holdings worth $1,563,514 on September 24, 2018, it also alleges that he sold 65.07% of his holdings worth $9,779,380 over the entire Class Period. (Am. Compl. ¶ 174.) Unless he subsequently acquired more stock after selling 90.91% of his shares worth approximately $1.5 million in September 2018, it would be impossible for the approximately $9.8 million worth of stock he acquired over the entire Class Period to constitute 65.07% of his holdings. The Court assumes that for Kalb and the other Defendants, this disconnect is explained by the fact that they acquired a substantial number of shares during the Class Period.

Kennedy's sales on the day the REDUCE-IT results were announced, on which the share price sharply jumped after a period of low value, reflected the executives "rationally monetiz[ing]" their shares. (*Id.* at 50–51.) Defendants contest Plaintiffs' characterization of the percentages of shares the Individual Defendants sold because the Amended Complaint "wrongly ignores their exercisable options." (*Id.* at 51.) Further, the Individual Defendants offer their Rule 10b5-1 plans, which they contend show that the Individual Defendants' trades were almost all planned prior to the Class Period. (*Id.* at 52–54.)

On balance, the Individual Defendants' stock sales somewhat contribute to an inference of scienter here, albeit weakly. In Plaintiff's favor, the value of the stock the three Individual Defendants sold was over $83 million, a significant amount. The Amended Complaint alleges that over the entire Class Period, Thero sold 24.30% of his shares; and during a portion of the Class Period—from the announcement of the REDUCE-IT results until the issuance of Judge Du's decision—Kennedy sold 89.19% of his shares and Kalb sold 65.07%. (*Id.* ¶¶ 173–75.) The size of these sales in comparison to the Individual Defendants holdings is unusual and supports Plaintiffs' position. *In re Suprema Specialties*, 438 F.3d at 278 (finding complaint "plausibly alleged that the sales were not normal or routine" for defendant officers who each "is alleged to have sold over 30 percent of his holdings"); *see also In re: Enzymotec*, 2015 WL 8784065, at *19 (finding complaint alleged stock sales "unusual in scope" where one defendant sold 35% of his total holdings and another sold 42%).[33] Likewise somewhat supporting this inference is the fact that two Defendants—Kennedy and Kalb—sold significant portions of their holdings on the day the REDUCE-IT results were announced, (Am. Compl. ¶¶ 173–74), and two Defendants—Thero and

[33] As noted above in the section addressing Defendants' exhibits, the Court does not consider Defendants' re-calculation of the percentages of the Individual Defendants' sales and holdings to account for their exercisable options, as that annex relies on documents not submitted to the Court in conjunction with Defendants' Motion for its data. (Annex E.)

Kennedy—did not sell any stock in the two years prior to that day, (*id.* ¶¶ 174–75). *See McDermid v. Inovio Pharms., Inc.*, 520 F. Supp. 3d 652, 654 (E.D. Pa. 2021) (finding unusual that defendants had not "sold stock in the year-and-a-half leading up to their 2020 sales").

However, the stock sales alleged in the Amended Complaint are a far cry from the "ship's captain exiting into the safety of a lifeboat while assuring the passengers that all is well" that Plaintiffs argue. (ECF No. 65 at 48 (quoting *In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 67 (2d Cir. 2001)).) As the Third Circuit has explained, "the pure percentage of holdings sold tells only part of the story. Courts have routinely found that even large percentages of holdings sold at first blush appearing suspicious are not sufficient to infer scienter when other factors, such as the timing of the relevant sales, weigh against that inference." *In re Hertz*, 905 F.3d at 121. The fact that the Class Period stretched 31 months cuts against inferring scienter when the company's officers sold significant amounts of stock during that period. *In re Burlington Coat*, 114 F.3d at 1424 (observing that because "corporate executives are compensated in terms of stock and stock options," it is not unusual that "these individuals will trade those securities in the normal course of events"). Thus, executive stock sales following the rise in stock price is not unexpected. *See In re Party City Sec. Litig.*, 147 F. Supp. 2d 282, 312 (D.N.J. 2001) ("Trading following public announcements simply evidences compliance with the securities laws."). The significance of Kalb and Kennedy selling large portions of their shares on the day the REDUCE-IT results were announced is lessened by the fact that Thero—who made the vast majority of the statements that Plaintiffs challenged—did not sell any stock that day, (Am. Compl. ¶ 170); had the Individual Defendants in fact known since 2011 (when they allegedly "buried" the Kurabayashi Study in the Form 1449) that the patents were vulnerable, one would have expected them all, including the CEO, to unload their shares when the price spiked after the REDUCE-IT results were announced.

A review of the Individual Defendants' publicly filed Individual Form 4s further mitigates the suspiciousness of the stock sales.[34] While the Court agrees with Plaintiffs that it cannot judicially notice the Rule 10b5-1 plans themselves, Courts routinely consider publicly-filed Form 4s (which here reference the Rule 10b5-1 plans). *See In re Hertz Glob. Holdings, Inc. Sec. Litig.*, No. 13-7050, 2017 WL 1536223, at *22 n.10 (D.N.J. Apr. 27, 2017), *aff'd*, 905 F.3d 106 (3d Cir. 2018) (considering Form 4s in deciding motion to dismiss and noting "it can take judicial notice of the public filings showing that the challenged sales by the defendants were made pursuant to 10b5-1 plans"); *see also Amarin II*, 2021 WL 1171669, at *9; *In re Merck Co., Inc., Sec., Derivative & "Erisa" Litig.*, No. 05-1151, 2006 WL 8460903, at *4 (D.N.J. Jan. 20, 2006) ("It is . . . without dispute that SEC Forms 4 and 5 are in fact SEC filings" subject to judicial notice.). A significant portion of the suspicious sales alleged in the Amended Complaint—indeed, almost the entirety of Kalb's and Kennedy's—were of the Individual Defendants' stock options that vested. (Exs. 63–65 (showing that Individual Defendants' stock sales occurred the same day or shortly after they were purchased at option prices).) Although the sale of stock options may still contribute to an inference of scienter, it is somewhat less because the "proceeds were the result of accumulated stock options and were an intended part of their overall compensation package." *Advanta*, 180 F.3d at 541 (citing *In re Burlington Coat*, 114 F.3d at 1424).

More importantly, almost every sale for all three Individual Defendants was entered into pursuant to a Rule 10b5-1 plan. "Pursuant to SEC Rule 10b5-1, a person's trading is not 'on the

[34] Defendants contend that it is "plaintiff's burden to plead suspicious stock sales, including that any 10b5-1 plan providing for the sales was entered into during the [class period] and at a suspicious time." (ECF No. 58-1 at 53 n.52.) Plaintiffs respond that "the existence of a Rule 10b5-1 Trading Plan is an affirmative defense that must be pled and proved." (ECF No. 65 at 55.) Both parties' positions go too far. While Courts in this District routinely consider Rule 10b5-1 plans in determining whether scienter is adequately pled, the cases do not support imposing a "burden" on Plaintiffs to affirmatively plead how the Rule 10b5-1 plans do not undermine the scienter allegations.

basis of' material non-public information, such as the allegedly fraudulent practices here, if the person adopted, and sold their securities pursuant to a written trading plan consistent with the terms of Rule 10b5-1." *In re Synchronoss Techs., Inc. Sec. Litig.*, No. 17-2978, 2019 WL 2849933, at *16 (D.N.J. July 2, 2019) (discussing 17 C.F.R. § 240.10b5-1(c)(1)). Courts in this district hold that "[t]rades made under automatic trading plans are of minimal value in establishing an inference of scienter." *Lovallo v. Pacira Pharm., Inc.*, No. 14-6172, 2015 WL 7300492, at *13 (D.N.J. Nov. 18, 2015) (citing *Avaya*, 564 F.3d at 279); *see also In re Synchronoss Sec. Litig.*, 705 F. Supp. 2d 367, 410 n.56 (D.N.J. 2010); *In re Audible Inc. Sec. Litig.*, No. 05-1027, 2007 WL 1062986, at *12 (D.N.J. April 3, 2007). Here, the public Form 4s note that every trade of all three Individual Defendants—except for approximately $2.4 million of sales by Thero in November 2020—were made "pursuant to a Rule 10b5-1 trading plan previously adopted" by the Individual Defendants. (Exs. 63–65.)[35] This further undercuts the inference Plaintiffs draw from Defendants' stock sales.

Cutting against scienter, Defendants argue that Amarin's investment of "hundreds of millions of dollars" in Vascepa's development weakens any inference of intent to defraud. (ECF No. 58-1 at 60.) Indeed, the history of Amarin's prosecution of its patent application before the

[35] The only sales that were not pursuant to the Rule 10b5-1 were Thero's two November 2020 sales of 567,405 shares worth a combined $2,318,569. (Am. Compl. ¶ 170.) The two sales were made months after Judge Du's March 2020 decision and at a share price of $4.13 and $4.07, well below the price at which the other sales alleged in the Amended Complaint were made. (*Id.*; *see also* Ex. 63 at 7.)

Plaintiffs argue that the Rule 10b5-1 plans were entered into fraudulently while Defendants knew the patents would be invalidated, eliminating any cleansing effect the plans could have. (ECF No. 65 at 55–56); *see Villare v. Abiomed, Inc.*, No. 19-7319, 2021 WL 4311749, at *21 (S.D.N.Y. Sept. 21, 2021) (finding a Rule 10b5-1 plan does not undermine scienter when it is "entered into or strategically amended to take advantage of an inflated stock price or insider information"). But a plaintiff cannot sidestep the Rule 10b5-1 plans by "conclusory" allegations of strategic use of the plans. *Id.* (citing *Koplyay v. Cirrus Logic, Inc.*, No. 13-790, 2013 WL 6233908, at *6 (S.D.N.Y. Dec. 2, 2013)). Plaintiffs allege that Defendants knew of the patents' vulnerability since at least 2011 when they sought patent protection for Vascepa. Given this long time frame, it is to be expected that the executives would have entered a Rule 10b5-1 plan at some point. Plaintiffs cannot rely on their claim of Defendants' decade-long deceit in order to argue that any action taken within that period—like entering into the plans—supports their inference of scienter.

USPTO and defense of same in the Nevada Litigation—as alleged in great detail in the Amended Complaint and chronicled in Amarin's SEC filings—evidences the significant efforts Defendants put into receiving their patents over the decade before Judge Du's decision. (*See* Am. Compl. ¶¶ 55–154; *see also* Exs. 1–62.) Defendants' statements alleged in the Amended Complaint also reference Amarin's significant investment in building infrastructure to accommodate expanded application and demand for Vascepa. For example, in a February 2020 SEC filing, Thero stated "we believe that a U.S. sales force of 800 sales representatives, supported by our other promotional activities, is positioned to make Vascepa a multibillion-dollar brand." (*Id.* ¶ 131.)[36] The Amended Complaint's allegation that Defendants bet the company on receiving and maintaining patent protection when they knew the patents could be undone by the consideration single study they failed to disclose is implausible. *See In re Celgene*, 2019 WL 6909463, at *13 ("[I]t is not plausible (absent specific contrary evidence) to believe that Celgene would continue with this large-scale, expensive Phase III trial merely for the sake of appearances."); *see also City of Edinburgh*, 754 F.3d at 170 ("Moreover, the initiation of Phase 3 cost millions of dollars and required FDA approval, rendering it improbable that defendants would have continued if they did not believe their interpretation of the interim results or if they thought the drug a complete failure.").[37]

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[36] In March 2021, Thero informed investors that Amarin was "doubling the size of our sales force" in order to focus on what Amarin considered a "global opportunity." (Am. Compl. ¶ 136; *see also id.* ¶ 114 ("We are very excited about the potential for Vascepa to help millions of patients and we are acting accordingly to expand on our established commercial foundation, including existing broad managed care coverage and extensive key opinion leader support."); *id.* ¶ 115 ("Following REDUCE-IT success, we have been in an active dialogue with companies in our supply chain as well as with certain companies that might be added to our supply chain. To ensure that we can further increase our supply capacity.").)

[37] *See also Gompper v. VISX, Inc.*, 298 F.3d 893, 897 (9th Cir. 2002) (finding no scienter inference from fact that company sued its competitors for patent infringement because "it is equally if not more plausible that [the company] consistently initiated litigation in defense of its patents because it and its officers believed the patents were valid"); *Cozzarelli v. Inspire Pharms.*, 549 F.3d 618, 627 (4th Cir. 2008) (finding inference of scienter undercut where the "complaint portrays [defendant's drug] as the 'lead development product' on which [defendant's] future as a company depended" because it was "improbable that

Tying these pieces together, the Court conducts a "holistic review" of the Amended Complaint to weigh the inferences for and against scienter. *In re Hertz*, 905 F.3d at 121. Here, the "opposing inference one could draw from the facts alleged" is stronger than the one Plaintiffs draw from their allegations. *Tellabs, Inc.*, 551 U.S. at 324. Certainly, the facts Plaintiffs pled create the inference that the Individual Defendants were aware of and involved with the Nevada Litigation, that they promoted Vascepa's use after the REDUCE-IT results were announced, and that they were optimistic about the strength of the MARINE patents and Vascepa's financial outlook. Likewise, Plaintiffs have alleged that the Individual Defendants' stock sales created the motive to make material omissions or misrepresentation, which offers tepid support for their scienter allegations.

However, the Amended Complaint fails to allege facts supporting a strong inference that Defendants knew or should have known that they would lose patent protection for Vascepa. Plaintiffs' case relies on Defendants knowing that the patent litigation was likely to be invalidated because of their knowledge that the Kurabayashi Study had been improperly "concealed" from the patent examiner or otherwise "buried." As explained in the preceding sections, Plaintiffs have not pled with particularity any facts supporting these assertions. Even had *someone* at the company thought the Kurabayashi Study would eventually undermine Amarin's patents, Plaintiffs have not alleged any facts suggesting that this information was shared with the named Individual Defendants. And while Plaintiffs are not required to allege scienter via any specific avenue, the absence of any allegation from inside the company—from a confidential witness or internal document—that Defendants did not believe in the strength of their patents is significant. *See Sapir*

[defendant] would stake its existence on a drug and a clinical trial that the company thought was doomed to failure").

v. Averback, No. 14-7331, 2016 WL 554581, at *10 (D.N.J. Feb. 10, 2016) ("Amended Complaint fails to cite a single document or witness that corroborates allegations of scienter."). Put differently, Plaintiffs do not allege that any of the Japanese studies they point to were concealed by Defendants or not in the public domain. Rather, they argue that Defendants should have weighed the evidence differently from the outset—as Judge Du eventually did in invalidating the patents rather than as the USPTO did in granting them—and avoided making any statements about the company's future that depended on Amarin defending its patents.

The more plausible inference drawn from the Amended Complaint's allegations is that Defendants honestly believed in their patents and Amarin's opportunity to expand its business based on the strength of its intellectual property. Plaintiffs allege that Defendants knew the patents should not be issued since Amarin first sought patent protection in 2011. For Plaintiffs to be correct, Defendants would have had to work for almost a decade—conducting long-term studies, interacting with regulatory bodies, advocating to the USPTO, suing their competitors, forcefully litigating from the district court to the Supreme Court—knowing that the patents would be invalidated and seeking to profit from their stock in the interim. Nothing in the Amended Complaint suggests such deception on the part of the Defendants. Thus, Plaintiffs do not provide sufficient allegations to support a "strong inference" of scienter. *See* 15 U.S.C. § 78u–4(b)(2).[38]

* * *

[38] Plaintiffs argue that because they adequately alleged scienter as to each Individual Defendant, their scienter is imputed to Amarin and they have therefore adequately pleaded Amarin's scienter. (ECF No. 65 at 47.) However, the Court finds that Plaintiffs have not alleged a strong inference of scienter with respect to the any Defendant, including Amarin.

Therefore, Plaintiffs have not met the heightened pleading standard as required by the PSLRA to plead either an actionable misstatement or omission or scienter.[39]

C. MOTION TO DISMISS SECTION 20(A) CLAIM

Against the Individual Defendants, the Amended Complaint alleges violations of Sections 20(a) and 20A of the Exchange Act, 15 U.S.C. §§ 78t(a), 78t-1. Section 20(a) control person liability "'is derivative of an underlying violation of Section 10(b) by the controlled person.' Inasmuch as there cannot be Section 10(b) liability here, the individual defendants cannot be liable" under Section 20(a). *Rahman*, 736 F.3d at 247 (quoting *Avaya*, 564 F.3d at 252). Likewise, insider trading claims against corporate insiders fail where plaintiffs have "failed to adequately plead a predicate section 10(b) violation." *City of Edinburgh*, 754 F.3d at 175.

Therefore, because the Court finds that Plaintiffs fail to state a claim under Section 10(b), the Amended Complaint's counts alleging Section 20(a) and 20A claims (Counts Two and Three) must also be dismissed without prejudice for failure to state a claim.

D. DRABEK'S STATUS ON THE CAPTION

Finally, Defendants request that the Court strike Warren Drabek from the case caption because the Amended Complaint does not "explain[] why his addition is necessary at this time." (ECF No. 58-1 at 63.) Defendants argue that Drabek was not named as a Plaintiff in either of the two prior complaints and that he never sought appointment as lead plaintiff. (*Id.* at 64.) Defendants contend that Drabek's inclusion is a "tactic" the Court should prevent. (*Id.* at 65.)

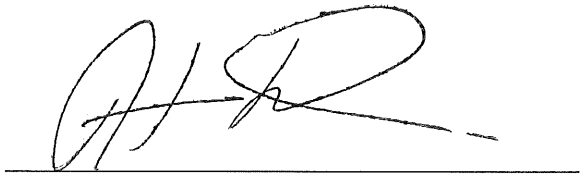
The Court agrees with Plaintiffs that Defendants do not cite any legal authority or concrete reasoning behind this request. (ECF No. 65 at 64–65.) Defendants do not adequately explain how

[39] Because the Court has concluded that Plaintiffs have failed to sufficiently plead the first two elements of a securities fraud claim, it is unnecessary to address Plaintiffs' allegations of loss causation.

Drabek's inclusion is a "tactic" or why it is improper. Absent any rationale or authority for Defendants' request, the Court declines to address Drabek's status in this action at this time and will deny Defendants' request.

CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss is **GRANTED**, and Plaintiffs' Complaint is hereby **DISMISSED** without prejudice. An appropriate Order accompanies this Opinion.



ROBERT KIRSCH
UNITED STATES DISTRICT JUDGE

Dated: September 25, 2024